EXPLANATORY NOTES

Health and Care Act 2022

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EXPLANATORY NOTES—HEALTH AND CARE ACT 2022

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HEALTH AND CARE ACT 2022

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Health and Care Act which received Royal Assent on 28 April 2022.

- These Explanatory Notes have been prepared by the Department of Health and Social Care in order to assist the reader in understanding the Act. They do not form part of the Act and have not been endorsed by Parliament.

- These Explanatory Notes explain what each part of the Health and Care Act will mean in practice; provide background information on the development of policy; and provide additional information on how the Act will affect existing legislation in this area.

- These Explanatory Notes might best be read alongside the Act. They are not, and are not intended to be, a comprehensive description of the Act.

Table of Contents

Subject	Page of these Notes
Overview of the Health and Care Act	**5**
Policy Background	**6**
Merging NHS England, Monitor and NHS Trust Development Authority	6
Mental Health Financial Reporting	7
Mandate and financial directions to NHS England	7
Funding for service integration	8
Integrated Care Boards and Integrated Care Partnerships	8
Collaborative Commissioning	9
Triple Aim	9
Duty to Cooperate	9
CQC Reviews of Integrated Care Systems	10
Secretary of State's duty to report on workforce systems	10
Power of Direction – Secretary of State public health functions	11
Secretary of State power to direct NHS England	11
Reconfigurations	12
New NHS Trusts	13
Capital spending limits over Foundation Trusts	14
Joint Committees	15
Joint Appointments	15
The NHS Payment Scheme	15
Patient Choice	15
Procurement of clinical healthcare services	16
Modern Slavery and Supply Chains	16
Competition	17
Special Health Authority Time Limits	17
Abolition of LETBs	17
Mandatory reporting of industry payments to the healthcare sector	18
Adult social care information	19
Information standards	19
Improving sharing of information	20
The Health and Social Care Information Centre	21
Information	21

Transfer of functions between Arm's Length Bodies 21
Health Services Safety Investigations Body 22
Virginity Testing 23
Hymenoplasty 23
Pharmacy Reimbursements 25
International Healthcare 26
Adult Social Care Assurance 28
Adult Social Care Intervention 29
Cap on Care Costs 29
Hospital Discharge 30
Medicine Information Systems 31
Children and Young People 32
Provision of Social Care Services: financial assistance 33
Professional Regulation 33
Medical Examiners 35
Organ Tourism 35
Human Fertilisation and Embryology: Storage of Gametes and Embryos 36
Advertising of less healthy food and drink 38
Hospital Food Standards 39
Food information for consumers: power to amend retained EU law 40
Water Fluoridation 40
Children's Palliative Care 41
Permitted locations for abortion treatment 41
Cosmetic Regulation 41
Mandatory training for learning disabilities and autism 42

Territorial extent and application 44

Commentary on provisions of the Act 45

Part 1: Health Service in England: Integration, Collaboration and Other Changes 45
NHS England 45
Integrated Care Boards 51
Integrated Care Boards: Functions 56
Integrated Care Partnerships 66
Integrated Care System: Financial Controls 66
Integrated Care System: reviews and further amendments 69
Merger of NHS bodies etc. 70
Secretary of State's functions 71
NHS Trusts 76
NHS Foundation Trusts 80

NHS Trusts and NHS Foundation Trusts: transfer schemes 83
Joint Working and Delegation of Functions 87
Collaborative Working 89
NHS Payment Scheme 91
Patient Choice and Provider Selection 93
Competition 96
Miscellaneous 97
Part 2: Health and Adult Social Care Information 100
Part 3: Secretary of State's Powers to Transfer or Delegate Functions 111
Part 4: The Health Services Safety Investigations Body 115
Introductory 115
Investigations 118
Reports 120
Investigatory Powers etc 122
Protection of Material Held by the HSSIB 124
Relationship with other bodies 127
Oversight of functions 128
Offences: supplementary 129
Supplementary 129
Part 5: Virginity Testing and Hymenoplasty Offences 130
Virginity testing offences: England and Wales 130
Virginity testing offences: Scotland 132
Virginity testing offences: Northern Ireland 132
Consequential Amendments 136
Part 6: Miscellaneous 138
Pharmaceutical services 138
International Healthcare 139
Social Care: Regulation and Financial Assistance 140
Professional Regulation 144
Medical Examiners 145
Organ trafficking 147
Human Fertilisation and Embryology 147
Food and Drink 151
Fluoridation of Water Supplies 158
Child Safeguarding: Information Sharing 159
Disability and autism training 160
Part 7: General 161
Related documents 164
Annex A – Territorial extent and application in the United Kingdom 166
Subject matter and legislative competence of devolved legislatures 166

Annex B – Hansard References 167

Annex C – Progress of Bill Table 169

Overview of the Health and Care Act

1 The key purpose of the Health and Care Act is to give effect to the policies that were set out as part of the NHS' recommendations for legislative reform in the NHS 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 Act:

- Promotes local collaboration;
- Allows for the reform of the NHS procurement rules;
- Improves accountability and seeks to enhance public confidence in the health and care system; and
- Delivers a range of targeted measures to support people at all stages of life.

3 The Act builds on recommendations for reform set out by NHS England in the NHS Long Term Plan published in 2019. Enshrining the NHS Long Term Plan in legislation was also a Conservative Manifesto Commitment in the 2019 General Election.

4 The Act also contains provisions relating to social care, public health and quality and safety in the NHS. These are designed to address specific problems or remove barriers to delivery and to maximise opportunities for improvement, and have, in some cases, been informed by the experience of the pandemic.

5 The Act contains 7 parts with 19 Schedules addressing a range of issues relating to health and social care. The Act 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).

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 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 operated under the name 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, while 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 Prior to the Act, NHS England and NHS Improvement had already 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). There were limits on the extent to which NHS England and NHS Improvement could collaborate under that statutory framework. For instance, NHS England and NHS Improvement were assigned distinctive and non-shareable functions, and required separate boards including separate chairs, CEOs and non-executive directors for the two organisations.

11 The Act enables the functions of the previous three national statutory bodies responsible for the NHS - the NHS Commissioning Board, Monitor and the TDA — to be moved into a single body. The formation of the new NHS England will provide national leadership which speaks with one voice to providers, commissioners and local health systems; will remove potential duplication; and use collective resources more efficiently and effectively to support local health systems and ultimately make effective use of public money.

12 The Act transfers the functions of Monitor and the TDA to NHS England and abolishes Monitor and the TDA.

Mental Health Financial Reporting

13 Ensuring public clarity about mental health funding, particularly the proportion of overall health services funding being spent on mental health services, is seen as an important way to measure "parity of esteem"– valuing mental health equally to physical health.

14 The Act therefore seeks to strengthen the accountability and transparency on spending relating to mental health. The Act will place a requirement to publish before the start of each financial year whether NHS mental health expenditure is expected to increase in the amount and proportion as compared to the previous year. It is expected that this expenditure will include integrated care boards' baseline spend within scope of the Mental Health Investment Standard, which covers all spending on mental health from an integrated care board's core allocations; NHS England service development fund spending on mental health; and specialised commissioning spending on mental health. NHS England and integrated care boards will then have to report back on their performance against this expectation as part of their respective annual reporting.

Mandate and financial directions to NHS England

15 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 of the NHS Act 2006.

16 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.

17 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.

18 The mandate remains the primary statutory mechanism for government to set objectives and requirements for the new NHS England. However, this Act makes the mandate duty more flexible, so that a mandate can be revised at any time, ensuring there is always a mandate in place, and will remain in force until it is revised by a new mandate. This flexibility strengthens 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. Within this context, however, the mandate will continuously include objectives on cancer that are expressed in terms of outcomes, and these objectives will have a priority over other objectives in the mandate that relate specifically to cancer. There continues to be a legal duty, under section 13A(8) of the NHS Act 2006, 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. NHS England will not be required to revise its own business plan should the mandate be revised during the period the plan applies but will need to set out in its annual report the extent to which, in that year, it met any objectives or requirements specified in the mandate for the relevant year.

19 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.

20 As a consequence of removing the statutory link between the mandate and the annual financial cycle, NHS England's annual limits on capital and revenue resource use can be set through financial directions from the Secretary of State. Such directions will be published and laid 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. The Act requires NHS England to exercise its functions with a view to ensuring that, in respect of each financial year, it does not exceed such limits specified in a direction by the Secretary of State.

Funding for service integration

21 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 (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.

22 The Act puts in place stand-alone powers for directions to be given to NHS England and to integrated care boards 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.

23 Previously, the legal basis for the allocation of the BCF relied on ministers setting a requirement each year in the NHS mandate to ringfence funding from commissioners' budgets.

24 A stand-alone power ensures that the BCF continues to function as it previously did 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.

Integrated Care Boards and Integrated Care Partnerships

25 Prior to this Act, CCGs were responsible for the planning and commissioning of health services in local areas. Since 2016, health and care organisations increasingly worked 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 accelerated this change.

26 The Act provides for the establishment of statutory integrated care boards and statutory integrated care partnerships.

27 The integrated care board takes on the commissioning functions of CCGs as well as some of NHS England's commissioning functions. However, an integrated care board is not simply a larger CCG but is expected to work differently in practice – its governance model reflects the need for integration and collaboration across the system. It has the ability to exercise its functions through place-based committees (while remaining accountable for them) and is directly accountable for NHS spend and performance within the system.

28 The integrated care board, as a minimum, includes 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. Integrated care boards will also need to ensure they have appropriate clinical advice when making decisions and that at least one ordinary member has knowledge and experience in connection with services relating to mental illness.

29 Each integrated care board and its partner Local Authorities will be required to establish an integrated care partnerships. The integrated care partnership can bring together health, social care, public health and representatives from the wider public space where appropriate, such as social care providers or housing providers.

30 An integrated care partnership is tasked with developing a strategy to address the needs assessed by Health and Wellbeing Boards under section 116 of the Local Government and Public Involvement in Health Act 2007 in respect of the relevant integrated care board area. The integrated care board, NHS England and local authorities will have to have regard to that plan when making decisions.

Collaborative Commissioning

31 Previous NHS legislative mechanisms made it difficult for the health and care system to work collaboratively and flexibly across different geographical footprints, forcing some local systems to adopt complex workarounds to be able to align their decisions and pool budgets. In practice, these arrangements were potentially cumbersome and difficult to manage and risked slow decision-making processes.

32 The Act makes a number of technical legislative changes to remove barriers and bureaucracy which could get in the way of delivering high-quality care to patients.

33 The Act makes it easier for integrated care boards to commission services collaboratively with other integrated care boards and other system partners by permitting a wider set of arrangements for joint commissioning, pooling of budgets and delegation of functions.

Triple Aim

34 The Act introduces a new duty on NHS organisations to consider the effects of their decisions on the better health and wellbeing of the people in England, 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". This duty should facilitate the tackling of inequalities, and it is made clear in the Act that the duty requires inequalities in health and wellbeing and the benefits from services to be part of the considered.

35 The previous legislative framework potentially led organisations to work primarily in the best interest of their own organisations and their own immediate patients - but did not support the delivery of integrated, patient-centred care.

36 This new duty requires organisations to think about the interests of the wider system and will provide common, system-wide goals that need to be achieved through collaboration, which includes NHS organisations' role in tackling disparities in health.

Duty to Cooperate

37 The Act 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.

38 New guidance will give organisations greater clarity about what the duties to cooperate mean in practice, helping build on the innovation, working relationships and positive behaviours that had been seen during the covid pandemic period in particular.

CQC Reviews of Integrated Care Systems

39 The Act introduces a new duty on the Care Quality Commission (CQC) to conduct reviews of the integrated care system (integrated care boards, local authorities and their system partners working collectively).

40 These reviews assess the provision of NHS care, public health, and adult social care within the integrated care board area. They consider how well the integrated care boards, local authorities, and CQC registered providers discharge their functions in relation to the provision of care as well as the functioning of the system as a whole, which will include the role of the integrated care partnership. The CQC is required to publish a report, providing an independent assessment of the health and care in integrated care systems.

41 The Act requires the Secretary of State to set the priorities and objectives of these reviews, with a requirement that priorities are set relating to leadership, integration, and quality and safety, and the CQC to determine the indicators of quality, methods, period, and frequency for these reviews with Secretary of State approval.

Secretary of State's duty to report on workforce systems

42 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, the TDA and individual employers, and, following changes made by the Act, the newly merged NHS England and integrated care boards) also have responsibilities for workforce planning and supply.

43 However, no one document exists or captures how the workforce planning and supply system operates at national, regional and local level. The Act places 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.

44 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).

45 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, integrated care boards 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.

46 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.

Power of Direction – Secretary of State public health functions

47 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.

48 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.

49 However, the Secretary of State could not require NHS England, or any other NHS body, to take on a delegated public health function. This potentially could have exposed the Secretary of State to a position where they were to effectively deliver an aspect of his or her public health duties. The Act creates a power for the Secretary of State to require, via directions, NHS England (or an integrated care board) to discharge public health functions delegated by the Secretary of State.

50 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.

51 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 Act, this 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.

52 To ensure transparency, the Secretary of State will need to publish any directions as soon as is practicable.

Secretary of State power to direct NHS England

53 The Secretary of State had responsibility for ensuring that NHS England, Monitor and the TDA were effectively carrying out their functions and retained ultimate responsibility for securing provision of services through the exercise of their functions, through powers such as those to set objectives for commissioners (for example by setting the mandate under section 13A of the NHS Act 2006), and to intervene in the event of significant failure (under section 13Z2 of the NHS Act 2006).

54 As explained above, the Act abolishes Monitor and the TDA and transfers their functions to NHS England. In recognition of the expanded powers and responsibilities of NHS England, the Act introduces an additional accountability mechanism to support the Secretary of State in his or her democratic oversight of NHS England.

55 The Act 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 its functions. Such directions apply only to functions of NHS England and sit alongside the pre-existing accountability mechanisms and processes for ensuring NHS England fulfil its duties to promote a comprehensive health service. 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 the Secretary of State has responsibility including social care and public health, to support integration and tackle broader priorities such as health inequalities.

56 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 power supplements these mechanisms by giving the Secretary of State the ability, where he or she 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 on NHS England's functions under section 13ZC must be made in the public interest, in writing, and published.

Reconfigurations

57 Reconfiguration is the term used to describe the management of service change in the NHS that has an impact on patients. The scale of possible change is broad, ranging from the small-scale closure of a GP surgery to a more significant replacement of a number of stroke units with a centralised hyper acute stroke unit.

58 Unless there is a need for urgent temporary reconfiguration of services, which is usually for reasons of patient safety, most service changes happen locally with consultation. Planned reconfigurations are developed at local or regional levels by commissioners. The Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 imposes requirements on relevant persons to consult the local authority where a substantial development of the health service or substantial variation in the provision of health services is proposed. This regime is intended to continue so that the day to day interactions between NHS commissioners, NHS providers and local authorities do not change. Local NHS commissioners will continue to be accountable to NHS England for the discharge of their functions in these matters, including planning, consulting and delivering on service change proposals.

59 The Secretary of State, pre-Act, was only able to intervene in reconfigurations upon receiving a local authority referral relating to the adequacy of consultation, or whether the proposal was in the interest of the health service. Following a referral, the Secretary of State had a discretionary power to take certain decisions based on the grounds of the referral. The Secretary of State typically asked the Independent Reconfiguration Panel (IRP) to provide expert advice and recommendations. The Secretary of State considered all of the available evidence, the expert advice of the IRP and the impacts of the proposal before making a decision on the matter, which could include giving a direction to NHS England. While this approach was able to help with difficult cases, referrals often came very late in the process meaning Ministers had to account for service changes in Parliament without having been meaningfully engaged on them themselves.

60 The Act adds a new discretionary power to the NHS Act 2006 for the Secretary of State to call in and make a decision on a reconfiguration proposal. The Secretary of State will be able to use this call-in power at any stage of the reconfiguration process.

61 This power is intended to be used in 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.

62 To support this intervention power, the Local Authority referral power, which is set out in regulations made under enabling powers in section 244 of the NHS Act 2006, will be amended to reflect the new process. There is no intention to remove the local Health Oversight and Scrutiny Committee (HOSC) role or the requirement to involve them in reconfigurations.

63 Where a reconfiguration has been called in by the Secretary of State using the powers in the Act, there is a duty on NHS England, integrated care boards or NHS trusts and NHS foundation trusts to provide any information or assistance that the Secretary of State requires. This may include any representations that a HOSC, stakeholder, patient group or any other interested party have made, if applicable.

64 NHS England, an integrated care board or an NHS trust or NHS foundation trust must 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.

65 The Secretary of State will seek appropriate advice in advance of their decision to meet the legal duties placed on them - including in relation to value for money, reducing inequalities, and continuous improvement in the quality of health services - and subsequently publish their decision in a transparent manner.

66 The Secretary of State will publish guidance for NHS England, integrated care boards, NHS trusts and NHS foundation trusts about how they should be exercising their functions under this new process, as well as how the Secretary of State may exercise their functions during this new process. These NHS bodies must have regard to such guidance provided by the Secretary of State.

67 It is intended that guidance will also provide detail for NHS bodies on exercising their duty to notify the Secretary of State of reconfigurations and clarify how the Secretary of State may use expert advice, including advice from the Independent Reconfiguration Panel.

68 The Secretary of State will be able to exercise the call-in power at any stage of a reconfiguration process, and will also be able to be the catalyst for a reconfiguration where he or she thinks appropriate. This might occur before NHS England, integrated care boards, NHS trusts or NHS Foundation Trusts have notified the Secretary of State of a proposed reconfiguration but where the Secretary of State is aware of an emerging issue after stakeholders have raised the issue with the Secretary of State or information has been supplied from within DHSC.

New NHS Trusts

69 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. DHSC does not expect the provider landscape to drastically change and, to ensure flexibility in that landscape, the Act 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.

70 DHSC expects new Trusts to be established following an application from an integrated care board to the Secretary of State, with further guidance to be published in due course. The Act allows for transfer schemes to be made to allow NHS Trusts and Foundation Trusts to transfer assets, property and liabilities between themselves.

Capital spending limits over Foundation Trusts

71 The Department for Health and Social Care is allocated a capital funding budget by Parliament and the Treasury, which amongst other capital spending covers capital spending in, in respect of the NHS (e.g. buildings, equipment and IT).

72 From 1 April 2020, a major part of the NHS capital budget had been allocated to voluntary partnerships of NHS commissioners, providers and local authorities known as Sustainability and Transformation Partnerships (STPs) and integrated care systems, in system-wide envelopes. These envelopes were derived directly from the NHS' share of DHSC's total departmental capital budget. They were set for all NHS provider organisations within an integrated care system footprint for their annual business as usual operational investments (e.g. routine maintenance and replacing equipment), distinct from the specific nationally led programmes such as major new hospital builds.

73 Under the new framework of this Act, it is the role of the integrated care board to ensure system capital expenditure is affordable within such envelopes and to prioritise its spending plans in accordance with the system wide health needs between each of the system providers. The Act establishes a joint duty between the integrated care board and its partner Trusts and Foundation Trusts to prepare a plan setting out their use of planned capital resources.

74 NHS Trusts were previously set statutory annual capital expenditure limits by the TDA in accordance with their capital expenditure plans. Capital expenditure limits are now set by NHS England following its merger with the TDA and Monitor under the Act. Previously there was no limit set on NHS Foundation Trusts, which also have additional freedoms to borrow from commercial lenders and spend their own surpluses to fund capital projects. Capital expenditure by Foundation Trusts counts against the integrated care system capital envelope and DHSC's overall capital departmental expenditure limit (CDEL). Under previous statutory powers, there was a risk that a Foundation Trust may go ahead with an individual scheme or schemes using its own cash to invest in capital without considering the overall impact on the local system integrated care system capital envelope, or on the national capital budget. This created 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.

75 The Act gives 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 single financial year (or part of it) and the limit would automatically cease at the end of that financial year. The power is intended to be used where there is a clear risk of a system breaching its system capital envelope as a result of actions of a Foundation Trust, and the issue has not been resolved more informally.

76 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 and the method it will use to determine the capital expenditure limit. The power will be used proportionately and it is envisaged in a limited way. The guidance will outline the process before a limit is set, including notifications and consideration of views from the Foundation Trust and the integrated care board. The guidance will also set out the publication of the order so there is transparency in the process.

77 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.

Joint Committees

78 Legislation did not previously allow NHS providers (NHS Trusts and Foundation Trusts) and CCGs to come together to formally take joint decisions. The Act puts in place an express mechanism to allow integrated care boards and NHS providers to form joint committees, or indeed two or more providers, and to make joint arrangements and pool funds. This can be used to facilitate greater integration.

79 These joint committees could take advice from other organisations such as primary care networks, GP practices, community health providers, local authorities or from the voluntary sector.

Joint Appointments

80 This Act introduces the ability for NHS England to issue guidance on joint appointments between NHS bodies; NHS bodies and local authorities; and NHS bodies and Combined Authorities. Joint appointments have already been made to great effect, allowing organisations to explore innovative new workforce models and deploy staff in the most effective way possible. Given the increased integration facilitated under the Act, joint appointments will continue to be beneficial. The new statutory guidance-making power for NHS England, which NHS bodies are required to have regard to, will help to ensure joint appointments are used effectively, and prevent conflicts of interest.

81 Ahead of publishing any guidance, NHS England would consult with appropriate organisations.

The NHS Payment Scheme

82 The Act replaces the National Tariff with a new NHS payment scheme which gives the NHS more flexibility in how prices and rules are set, to help support the delivery of more integrated care at local levels.

83 The scheme will be published by NHS England, who will consult with integrated care boards as the new commissioners 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 integrated care board or NHS England, on behalf of the Secretary of State (known as section 7A and section 7B services, in reference to the relevant powers in the NHS Act 2006, as inserted by this Act).

Patient Choice

84 Section 75 of the 2012 Act provided for regulations to be made in relation to patient choice. Section 75 also covers procurement and is being repealed as part of this Act, which means the regulations covering patient choice would also be revoked. However, so that patients' rights to choice will continue to be protected, the Act will add similar powers including those relating to guidance and enforcement to the NHS Act 2006. The power to make guidance and powers in relation to the enforcement of patient choice will be held by NHS England, following the planned merger with Monitor, under this Act. NHS England will have powers to resolve any breaches of patient choice.

85 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 an appointment as an outpatient (with some exceptions). The Act will allow for these, and other aspects of patient choice, to be preserved through regulations made under new powers.

86 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.

Procurement of clinical healthcare services

87 The procurement reforms within the Act 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 Act provides a power to create, via regulations, separate procurement measures for these services. It is our intention to use these powers to remove the procurement of health care services for the purposes of the health service from scope of the Public Contracts Regulations 2015. The Act provisions also repeal Section 75 of the 2012 Act and the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

88 The Act enables the development of new measures for NHS and public health procurement, informed by public consultation, to reduce bureaucracy on commissioners and providers alike, and give decision makers the flexibility to use competitive tendering where it adds value.

89 These reforms will generally only apply to the procurement of clinical healthcare services. The procurement of non-clinical services, such as professional services or clinical consumables, will remain subject to wider rules governing public procurement. 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 services and other services or goods – for example, if a health care 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.

90 NHS England have previously consulted on the proposal to replace the current legislation with a new provider selection regime, and over 70% of respondents either agreed or strongly agreed with this proposal. The Department of Health and Social Care launched a further consultation on the details of the policy on 21 February 2022.

Modern Slavery and Supply Chains

91 Modern slavery encompasses the offences of slavery, servitude, forced and compulsory labour and human trafficking. The NHS has a significant role to play in combatting it, including through taking steps to ensure that NHS supply chains and business activities are free from ethical and labour standards abuses. Government relies on its suppliers for the delivery of many important public services and we expect the highest standards of business ethics from our suppliers and their agents.

92 The Act introduces a duty on the Secretary of State to carry out a review into the risk of slavery and human trafficking taking place in NHS supply chains, and to lay a report before Parliament on its outcomes.

93 The Act also requires the Secretary of State to make regulations setting out such provision as he thinks appropriate with a view to eradicating the use in the NHS in England of goods or services that are tainted by slavery or human trafficking. The regulations can, in particular, include steps that the NHS should be taking to assess the level of risk associated with their supply chains; provision in relation to procurement processes, including the basis on which

the NHS should exclude suppliers from a tendering process; and measures that should be included in contracts.

Competition

94 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 was given a concurrent duty to promote competition in the NHS, while it was clarified that the CMA had specific functions to investigate mergers between NHS Foundation Trusts. The CMA was also given a role in investigating contested licence conditions should significant numbers of providers object to them.

95 The NHS Long Term Plan 2019 called for a stronger emphasis on collaboration between organisations and a less central role for competition in the system.

96 The Act removes Monitor's competition functions 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.

97 The Act also removes 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.

98 The Act removes 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 licensing regime and the NHS Payment Scheme, in consultation with local leaders.

99 The CMA will retain its other functions in relation to regulating competition, such as within the private healthcare market, and within General Practice.

Special Health Authority Time Limits

100 The 2012 Act amended the 2006 Act to require that, where Special Health Authorities (SpHAs) are set up after 2012, their establishment orders must provide for their expiry within three years of their establishment. Variations could be made to that expiry date, but only to extend it for a maximum of three years at a time. The Act removes the three-year time limit for all SpHAs.

101 This time limit is deemed no longer necessary, as ministers intend the functions of all SpHAs to be enduring. The amendment also ensures that SpHAs established after 2012 (only the NHS Counter Fraud Authority at the point of these provisions coming into force), and those established before that date, are no longer in different positions. By removing this time limit, all SpHAs will be treated equally in legislation.

Abolition of LETBs

102 Local Education and Training Boards (LETBs) were established as statutory sub-committees of HEE under Chapter 1 of Part 3 of the Care Act 2014. They were set up to 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.

103 The Act abolishes LETBs as statutory sub-committees to enable HEE to develop and adapt its own flexible regional operating model to best deliver its objectives over time.

Mandatory reporting of industry payments to the healthcare sector

104 The Independent Medicines and Medical Devices Safety Review (the "IMMDS Review"), chaired by Baroness Cumberlege, reported in July 2020 on three medical interventions: Primodos (which is a brand of hormone pregnancy test used from the 1950s to 1970s), sodium valproate (a drug used to treat epilepsy) and pelvic mesh (a medical device used to support pelvic prolapse and urinary incontinence).

105 Recommendation number 8 of the report on the review (page 188) provided the following: "there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians".

106 This recommendation was made because of concerns about perceived and real conflicts of interest in the provision of healthcare and treatment, particularly when doctors have financial and other links with pharmaceutical and medical device companies. The report emphasised that responsibility for transparency in this regard should not only lie with the medical profession, but also with the pharmaceutical and medical devices industries.

107 Although there are existing reporting initiatives, participation is voluntary. The IMMDS Review (at paragraphs 2.53 to 2.57) identified a perception amongst patient groups that payments to clinicians could influence their practice, and that a voluntary scheme is not adequate to ensure transparency. Patient groups subsequently continued to make strong demands for a mandatory scheme.

108 The Government accepted the recommendation in principle and agreed to develop options "including making reporting mandatory through legislation". Sections 92 to 94 of the Act respond to this recommendation by creating powers that will enable regulations to require that payments and other benefits provided by pharmaceutical, medical device and other businesses to the healthcare sector are put into the public domain.

109 The sections allow regulations to place a requirement on manufacturers or commercial suppliers of health care products (or persons connected to them) to publish or provide to the Secretary of State information about payments they make or other benefits they provide to persons providing healthcare or persons who carry on activities connected with healthcare. This includes organisations who may not directly provide healthcare but who may influence it, for example through the education of healthcare professionals.

110 There are some circumstances in which the publication of information relating to a payment or other benefit may impact on delivering value of money in the healthcare sector or the attractiveness of the United Kingdom as a research destination, and it therefore may not be appropriate to require this information to be made publicly available. For example, where the NHS negotiates a confidential discount on medicines, it is not the intention that relevant companies will be required to publish or provide information about this payment given the impact this would have on the NHS's ability to achieve the best value for money. Therefore, section 92 provides that the Secretary of State has the ability to make provision in the regulations for exceptions to the requirement to publish or provide information, for example, to support the attractiveness of the United Kingdom's life sciences sector.

111 Section 92 enables the Secretary of State to exempt businesses from these requirements if the equivalent information is published elsewhere via an alternative reporting scheme which the Secretary of State considers renders compliance with the requirements imposed by the regulations unnecessary.

112 While the value of this policy is to enhance transparency and improve the data available to the public, this can only be realised if businesses comply. The Secretary of State will therefore be able to make regulations about enforcement of requirements in the regulations, including imposing financial penalties.

113 We consider there is benefit to introducing UK-wide regulations. This is consistent with the approach taken in medicines and medical devices regulations and would place consistent obligations on businesses, reduce potential loopholes and ensure we can achieve comprehensive coverage to the benefit of patients. In order to ensure regulations work for the whole of the United Kingdom the sections provide that the Secretary of State must seek the consent of the Scottish Ministers, Welsh Ministers or Department of Health in Northern Ireland before regulations are laid, where the regulations are within the legislative competence of the devolved legislatures.

114 Taken together, sections 92 to 94 enable the Secretary of State to make regulations which will deliver increased transparency of the relationship between businesses and the healthcare sector, provide patients with information on the relationships which may impact their healthcare and provide the public with information to enhance their trust in the health care system.

Adult social care information

115 Adult social care is governed by a national regulatory framework but is generally delivered at a local level by local authorities. Under normal circumstances, aggregated adult social care data is collected from local authorities once a year and is published by NHS Digital. Prior to this Act, there was 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.

116 The provisions in the Act reflect a view that data relating to care received by individuals is more useful than aggregate data in enabling the linking and use of data across health and adult social care to improve services and to monitor people's care through the whole care system. The provisions also aim to ensure consistency of data whether care is publicly arranged or arranged privately by individuals.

117 Alongside client data, being able to collect information from, and about, providers in a consistent way 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).

Information standards

118 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 by, 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.

119 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.

120 The changes in this Act arise from a desire to further improve the consistency with which information systems used by health and adult social care providers adopt a standardised approach to the collection, storage and processing of data. The aim is to enable the Secretary of State 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 just have 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

121 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.

122 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.

123 The Act introduces a power for relevant health or social care 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, does not fall under the power. In addition, the Act provides powers to make regulations that will enable the introduction of exceptions to the power, 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.

124 The duty to share anonymous information complements 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.

125 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.

126 Requiring, enabling, facilitating and encouraging more effective use of data will support other key provisions in the Act, for example provisions strengthening the duty to cooperate across

the health and care system, including integrated care boards, 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 efficiency and sustainability in relation to the use of resources.

The Health and Social Care Information Centre

127 The Health and Social Care Information Centre, known as NHS Digital, 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.

Information

128 The data provisions in the Act 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.

129 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.

Transfer of functions between Arm's Length Bodies

130 Arm's Length Bodies (ALBs) are bodies that have a role in the processes of national Government, but are not a part of it, and accordingly operate to a greater or lesser extent at Arm's Length from ministers. The health and social care ALB 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 for them; and Advisory NDPBs , which are not separate legal identities and consist of external experts operating in a personal capacity. Although not strictly ALBs, DHSC also has Expert Committees operating as part of DHSC, and sponsors one Non-Ministerial Department, the Food Standards Agency, which is fully independent and accountable to Parliament.

131 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.

132 These powers will allow the transfer, by regulations, of functions from one of a list of relevant NDPBs 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 listed NDPBs. These powers will not allow the Secretary of State's functions to be transferred to a NDPB, merely the exercise of those functions. Responsibility will remain with the Secretary of State.

133 There will be a full and transparent process when making regulations to transfer or provide for the exercise of functions. A formal consultation will take place, which will include the ALBs involved, and approval will need to be secured from both Houses of Parliament as the regulations are subject to the affirmative procedure.

134 Additionally, consent must be obtained from the Devolved Governments for any transfer within their legislative competence or that modifies the functions of the Welsh or Scottish Ministers, or a Northern Ireland Department.

135 The Executive Agencies are legally indistinguishable from the Secretary of State and, as such, there is no need for them to be separately included in these powers.

136 The NDPBs to remain out of scope, given their particular, technical, regulatory functions, are the Care Quality Commission, the National Institute for Health and Care Excellence, and the Health Service Safety Investigations Body (once it is created as a NDPB through this Act).

Health Services Safety Investigations Body

137 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 Act establishes 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 Health Services Safety Investigations Body (HSSIB).

138 The HSSIB is 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.

139 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.

140 The Act 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.

141 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.

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

143 This policy aligns 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).[1]

Virginity Testing

144 Virginity testing, also known as a hymen test or "two-finger" test, is defined by the World Health Organisation (WHO) as a gynaecological examination conducted under the belief that it determines whether a woman or girl has had vaginal intercourse.[2] The process involves placing two fingers or a medical instrument inside the vagina to check for an intact hymen (tissue at the vaginal opening). This can be a physical or a visual examination. There is no consensus around this definition as virginity testing can also be defined as checking for vaginal laxity (looseness) and examining the size of the vagina which could suggest vaginal intercourse. It must be noted that this definition is not widely used.

145 Virginity testing is widely regarded as a form of violence and abuse against women and girls which stems from a patriarchal and repressive attitude towards women, with women and girls being often coerced and forced into having a virginity test against their will. In early 2021, the then Secretary of State for Health and Social Care and the Home Secretary commissioned an intensive Departmental review into virginity testing.

146 The review concluded that virginity testing is not a medical procedure, but a vaginal examination with no scientific or clinical merit. Women and girls are often coerced or forced into virginity testing against their will. Virginity tests are carried out for cultural reasons and may be done before a young woman or girl gets married as proof of her "virginity" and so called "honour". Virginity testing can also be carried out in other circumstances, for example if a teenage girl is seen with a boy and there is a perceived need to "prove" that she is still a virgin. All stakeholders outlined that women and girls are often coerced or forced into having the "test" by their family members or their intended husband's family. It is most prevalent in highly conservative communities. It is widely accepted as a form of violence against women and girls that can have short- and long-term impacts. Virginity testing can be physically harmful, in some cases causing damage to the hymen, bleeding and infection. Stakeholders have explained that virginity testing can also lead to anxiety, depression and post-traumatic stress disorder and suicide, especially if performed without the patient's consent. There is anecdotal evidence that suggests girls as young as 13 are being subjected to virginity testing.

147 The review's finding and recommendations were published in the **Violence Against Women and Girls strategy** in July 2021, which states that virginity testing can have detrimental physical and psychological impacts on women and girls. In light of this decision, this Act therefore provides for the criminalisation of "virginity testing". Provisions in the Health and Care Act 2022 making it illegal to carry out, offer or aid and abet virginity testing in any part of the UK came into effect on 1 July 2022.

Hymenoplasty

148 Hymenoplasty is a procedure undertaken to reconstruct a hymen. This is done by suturing hymenal remnants together at the vaginal opening, or surgically reconstructing the hymen

[1] 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 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/445640/Learning_not_blaming_acc.pdf

[2] *Eliminating virginity testing: An interagency statement,* The World Health Organisation, 2018, p.4 https://apps.who.int/iris/bitstream/handle/10665/275451/WHO-RHR-18.15-eng.pdf?ua=1

with the purpose of making a woman bleed the next time she has intercourse (but is not guaranteed to do so), in order to give the impression that she has no history of vaginal intercourse. The hymen, once broken, does not disappear but leaves papillary projections. In a hymenoplasty these are trimmed and picked up with a stitch and then tied like a purse string. This will ultimately form some scar tissue. There is no guarantee that this will fully reform the hymen or cause bleeding when penetration is attempted. It can sometimes be advertised as "virginity surgery".

149 The hymen is a thin piece of skin that partially covers the vagina. It usually breaks during sex, but not always, and can be broken through using tampons, activities such as horse riding and other sports. This means that having a broken hymen cannot be used as an indication that a woman has had vaginal intercourse. Equally, an intact hymen also does not mean that sexual intercourse has not occurred, as a hymen can stretch to accommodate penile penetration. It is entirely normal for hymenal remnants to remain even after childbirth. The World Health Organisation is clear that the appearance of a hymen is not a reliable indication of absence of intercourse. The hymen also has very few blood vessels and therefore an absence of blood when having sexual intercourse for the first time is also not an indication that a woman has had previous sexual intercourse.

150 Following widespread concerns that women and girls were being forced and coerced into undergoing virginity testing and hymenoplasty, in early 2021 the then Secretary of State for Health and Social Care and the Home Secretary commissioned urgent policy work to determine if any government intervention, including legislation, is required, and if so, what the right legislative vehicle might be. The review's recommendations included the proposal to criminalise virginity testing, but not to legislate to ban hymenoplasty at the same time. The arguments for a ban were at the time not so clear cut, and the government committed to establishing an expert panel to review the procedure in more detail.

151 The Panel's report was published on 23 December 2021 alongside a background paper [Expert panel on hymenoplasty - GOV.UK (www.gov.uk)] which summarises the evidence gathered during the intensive review and other several other sources of evidence. This evidence includes an extensive literature review, position statements from Royal Colleges, recent campaigns and personal experience case studies. This also includes the conversation and positions put forward by the Moral and Ethical Advisory Group (MEAG) who were consulted prior to the establishment of the panel.

152 The Panel found that hymenoplasty is inextricably linked to virginity testing. Hymenoplasty is often undertaken by the same private clinics that offer virginity testing. If a woman or girl "fails" a virginity test, hymen repair surgery might be the logical next step. The continuing availability of hymenoplasty could serve as an incentive for families to seek virginity testing of women and girls. A failure to prohibit hymenoplasty would undermine the Government's commitment to address the violence against women and girls by criminalising virginity testing. It is a harmful practice that creates and exacerbates social, cultural and political beliefs that a women's value is based on whether or not she is a virgin before marriage.

153 There is no clinical benefit to hymenoplasty, nor any other procedure under a different name that seeks to reconstruct the hymen. The Royal College of Obstetricians and Gynaecologists (RCOG) does not provide any training or clinical guidelines on how to undertake this procedure, and the clinical risks of undertaking it are unknown, with no evidence to prove it has no adverse effects.

154 The Panel describes the physical and psychological risks of HP as including:

- Infection

- Acute bleeding during the procedure
- Scarring and narrowing of vaginal opening
- Reduced sensation/ increased sensation (pain rather than pleasure)
- Sexual difficulties
- Depression
- Anxiety
- Post-Traumatic Stress Disorder
- Reduced or no libido
- Suicide

155 The expert panel have confirmed that there is never a medical or clinical need to repair or reconstruct the hymen. In some very limited circumstances (not least because clinicians have other, non-surgical treatments available), there are procedures that are clinically necessary to remove hymenal remnants caused by external trauma or child birth. This would involve removing any remaining parts of the hymen to prevent bleeding, infection or discomfort to a woman. Such a procedure does not involve any reconstruction of the hymen but rather removes any remaining traces of the skin.

156 The government agreed with the panel's main recommendation and announced its intention to ban hymenoplasty when Parliamentary time allowed in the Women's Health Strategy Vision Document published on 23rd December 2021. The Health and Care Act 2022 has provided the earliest legislative vehicle to ban hymenoplasty.

157 As a cosmetic surgical procedure, hymenoplasty would not have otherwise been an offence if carried out with the patient's consent. The ban is therefore achieved through the creation of a new criminal offence. No other legislation would serve to prevent hymenoplasty. Sexual offences are not relevant because the surgery is not sexual in nature. The prohibition on female genital mutilation would not cover the surgery, because this only applies to mutilation of certain of the specific external genitalia. Professional regulation was considered by the expert panel, who concluded that this was insufficient to protect women from the risks of hymenoplasty. And in relation to offences against the person, while consent to the surgery may not be in place due to the pressure placed on women to undergo it, this would not necessarily always be the case.

158 Provisions in the Health and Care Act 2022 making it illegal to carry out, offer or aid and abet hymenoplasty in any part of the UK came into effect on 1 July 2022.

Pharmacy Reimbursements

159 The typical process by which Community pharmacies obtain medicines can be summarised as follows: wholesalers purchase stock from manufacturers, which they sell to pharmacies who in turn supply it to patients. This could be in accordance with a prescription, a serious shortage protocol, a patient group direction or a pandemic treatment protocol. The pharmacy then claims reimbursement from the NHS for the product supplied. This is according to the arrangements set out in determinations by either the Secretary of State, Welsh ministers or NHS England which are published monthly in the Drug Tariff. The legal basis for these arrangements is set out in section 164 of the NHS Act 2006 and section 88 of the National

Health Service (Wales) Act 2006. The Drug Tariff sets out a total payment package for the service provider that includes an amount that is referable to the cost of the product supplied and an amount that is referable to the service cost, for example doing the clinical check, advising the patient etc. Payments linked to the supply of products are termed reimbursement and in connection with service fees termed remuneration.

160 The assumption is that even if the service provider received the product for free, they will be reimbursed something for dispensing it. This precludes an arrangement whereby the Government or NHS centrally procures products and then requires community pharmacies to source them from the central supplier at no cost to the community pharmacy. Regardless of the fact that the community pharmacy has paid nothing for the product, the scheme of the Act is such that there is an obligation for them to be reimbursed for it, unless there is a statutory exemption that applies, which is now being added to.

161 We encounter problems with the system when not using a conventional supply chain, and this led to the unlicensed "specials" medicine amendments made to section 164 of the NHS Act 2006 and section 88 of the NHS (Wales) Act 2006 in 2017. Due to a lack of competition in the market for unlicensed medicines, and arrangements that meant that suppliers' list prices were paid (a factor that has been partially dealt with in other ways), there was no incentive for pharmacy contractors to seek value for money. Therefore, the Government has included provisions to allow the Secretary of State or Welsh ministers to make regulations to the effect that pharmacy contractors do not need to be reimbursed for unlicensed "specials" medicines that are centrally supplied free of charge to them, for example by the NHS or DHSC.

162 This provision seeks to add, in a limited way, further exemptions from the general obligation that community pharmacies needed to be reimbursed for the products supplied as part of pharmaceutical services in England and Wales, and as a corollary to that, to facilitate central purchasing. There are various reasons why the Department of Health and Social Care may now seek to centrally procure vaccines, immunisations or products used to treat a pandemic. For example, in a global health emergency, when pressures from global demand mean that central purchasing and direct supply to community pharmacies are critical to maintain continuity of supply for UK patients in England or Wales, Ministers may wish to use central procurement without the risks of wholesalers increasing prices or exporting the stock. The Government wishes to have the option to be able to supply the product "directly" free of charge to pharmacies, without needing to sell into the supply chain in order to allow the ordinary reimbursement arrangements to function. In these circumstances, the Department would not want to reimburse pharmacies as well as purchasing the stock, otherwise the Government would be paying twice for the product.

163 The additions made by the provision are restricted to vaccinations and immunisations, medicinal products used for the prevention or treatment of disease in a pandemic, and associated products such as diluents and syringes. This provision aims to strengthen the legal basis for these central purchasing scenarios while aiming to not radically change established NHS pharmaceutical service provision or payment mechanisms.

International Healthcare

164 International healthcare is a small and important element of general healthcare policy in the UK. 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).

165 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 European Union (EU). In anticipation of a possible no deal scenario, 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 the European Economic Area (EEA) or Switzerland if no bilateral arrangements were in place.

166 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 and Switzerland.

167 The Government is now looking to strengthen the UK's relationships with countries across the globe and improve international healthcare cooperation. The Reciprocal Healthcare provisions in this Act amend HEEASAA to enable the Secretary of State to also implement comprehensive reciprocal healthcare agreements with countries outside the EEA and Switzerland.

168 Prior to the provisions in this Act, the Secretary of State only had powers under HEEASAA to implement comprehensive reciprocal healthcare agreements within the EEA and Switzerland. The limited geographical scope of the powers in HEEASAA meant that the Secretary of State did not have the necessary powers to implement reciprocal healthcare agreements with countries outside of the EEA and Switzerland, including, for example, British Overseas Territories and Crown Dependencies, other than the ability to exempt individuals from charges for relevant NHS services.

169 As a result, although the UK entered into a number of reciprocal healthcare agreements with countries outside the EEA and Switzerland, such as with Australia and New Zealand, they were 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 entered into with countries outside the EEA and Switzerland, UK nationals could access emergency treatment should they require it, however, access to haemodialysis for kidney patients was restricted or not included within the scope of these agreements..

170 The provisions expanding HEEASAA to countries outside the EEA and Switzerland enable the Secretary of State to make regulations for the purpose of giving effect to healthcare agreements, including provision for the reimbursement of healthcare costs. The provisions also provide the devolved authorities (Scottish Ministers, Welsh Ministers and a Northern Ireland department) with a concurrent regulation making power to give effect to healthcare agreements in devolved areas of competence.

171 Further, the amendments to HEEASAA will enable the Secretary of State to make discretionary payments, in exceptional circumstances, but only in countries with which the UK has a reciprocal healthcare agreement. This remains a necessary power which will allow the Secretary of State to support UK nationals abroad where due to exceptional circumstances they require to access healthcare abroad but fall outside the scope of a reciprocal healthcare agreement.

172 They will extend the existing data sharing provisions in section 4 HEEASAA to Rest of World countries to provide a legal basis for facilitating data processing to support the making of payments and giving effect to healthcare agreements. This data sharing will be fully in line with UK GDPR.

173 Now the Government has a reciprocal healthcare agreement with the EU, this section also removes the power in HEEASAA to establish detailed unilateral healthcare arrangements as these are no longer needed.

174 No reciprocal healthcare arrangements are made or changed as a direct result of this legislation.

Adult Social Care Assurance

175 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.

176 The Act 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.

177 The CQC must 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 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.

178 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.

179 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.

180 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.

181 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 is amended by this Act so that there is a clear distinction between these "special reviews" or investigations, and the reviews to be carried out by the CQC under the new section 46A of the Health and Social Care Act 2008.

182 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 is amended by this Act to also apply to reviews conducted by the CQC under the new section 46A.

183 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 is amended by this Act so that the CQC may carry out inspections for the purposes of its reviews under new section 46A.

Adult Social Care Intervention

184 Part 1 of the Care Act 2014 sets out a wide range of care and support duties 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.

185 Section 164 of this Act inserts a new section 72A into the Care Act 2014. Section 72A contains powers for the Secretary of State to issue directions to local authorities where the Secretary of State is satisfied that they are failing or have failed to discharge their functions under Part 1 of the Care Act 2014 to an acceptable standard.

186 These powers are part of the approach to oversight and support of the adult social care sector, underpinned by other Act provisions to provide for data collection and routine CQC assurance of local authority performance. These new powers enable Secretary of State to intervene to secure improvement where necessary.

187 In light of these new intervention powers, two pieces of existing legislation will be amended:

a. Section 165 makes amendments to section 50 of the Health and Social Care Act 2008, so that in every case where the CQC considers that a local authority is failing to discharge its functions to an acceptable standard, it must inform the Secretary of State and must recommend any special measures it considers that the Secretary of State should take.

b. Section 164 makes amendments to section 7D of the Local Authority Social Services Act 1970, taking local authority duties under Part 1 of the Care Act 2014 out of scope of the powers conferred by section 7D.

Cap on Care Costs

188 The Care Act 2014 (the "2014 Act") contains provisions relating to adult care, support and health. Part 1 of the 2014 Act is intended to provide duties and responsibilities to local authorities in meeting the care needs of their population. Part 1 also includes powers for a local authority to charge for the cost of care and provisions to implement the changes put forward by the Commission on the Funding of Care and Support.

189 Section 15 of the 2014 Act establishes a cap on the amount that adults can be required to pay towards eligible care costs over their lifetime. These costs are either specified in a personal budget (under section 26) where the local authority is meeting the person's needs, or, once

commenced, in an independent personal budget (under section 28) where the local authority is not.

190 The amendments made in this Act were introduced in order to enable the introduction of a cap on the amount anyone in England will need to spend on their personal care over their lifetime. While the power to set a cap was already legislated for in the 2014 Act, the decision was made that the cap, and the way people meter (accrue costs) towards it, should operate differently to how the Government envisaged in 2014.

191 Prior to the amendments made by this Act, section 15 of the 2014 Act stated that people who receive financial support from the local authority will meter to the cap at the cost of care specified in their personal budget; this cost is met through a combination of local authority and individual contributions.

192 The Act provides that only the amount that the individual contributes towards these costs will count towards the cap on care costs, and so individuals will not reach the cap at a faster rate than their personal contributions.

193 The Act also makes technical changes to the 2014 Act to ensure the policy intentions for Personal Budgets and Independent Personal Budgets are reflected in legislation.

194 The legislation specifies the information which must be included when creating a Personal Budget, to ensure that all contributions made by the individual which ought to count towards the cap at the local authority determined rate are recorded in the Personal Budget – to bring it in line with the policy intention. This is aimed to ensure that Personal Budgets and Independent Personal Budgets work as they were originally intended when being used in conjunction with the cap.

Hospital Discharge

195 This section 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.

196 This section 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 recovery, where it is possible to make an accurate evaluation of their long-term needs.

197 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.

198 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.

199 This section also introduces a new duty for trusts and foundation trusts to, where appropriate, involve carers at the earliest opportunity in discharge planning for adult patients who are likely to need care and support after their hospital discharge. The section states that carers should be involved as soon as it is feasible after the trust begins making any plans relating to the patient's discharge. This section defines a carer as an individual who provides or intends to provide care for an adult, otherwise than by virtue of a contract or as voluntary work. It applies to carers of all ages, including young carers.

Medicine Information Systems

200 The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of DHSC. It acts on behalf of the UK's licensing authority[3], 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.

201 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.

202 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-focused 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 establishment of registries was recommended in the Independent Medicines and Medical Devices Safety (IMMDS) Review published on 8 July 2020.

203 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.

204 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 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.

205 To improve the existing monitoring of the use, benefits and risks of medicines and to improve patient safety, the Act creates powers through which one or more medicines information

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

systems 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.

206 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 section 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.

207 The Act provides a power to make regulations which will enable NHS Digital to collect a range of information about the use of medicines and their effects in the UK and to hold this data in one or more information systems. 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 of 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.

208 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 (c.3) (section 19). This Act amends that Act; this will ensure both powers are set out in the same piece of legislation.

Children and Young People

209 The transition to integrated care boards and integrated care partnerships provides an opportunity to improve the planning and provision of services to make sure they are more joined up and better meet the needs of babies, children, young people and families.

210 To ensure that the integrated care board specifically considers the needs of babies, children and young people, the Act requires the integrated care board to set out any steps it proposes to take to address the particular needs of children and young people under the age of 25, in the annual joint forward plan with its partner NHS Trusts and Foundation Trusts.

211 NHS England has committed that statutory guidance to integrated care boards will contain provisions for an integrated care board executive lead to be appointed to act as a "children and young people's lead", with responsibility for championing the needs of children and young people. To ensure child safeguarding and SEND duties receive sufficient focus in the integrated care board, NHS England statutory guidance will contain provision for the delegation of responsibility for these duties to an integrated care board executive lead. NHS England statutory guidance will also clarify that the integrated care board annual report should set out how the integrated care board has discharged their duties in relation to child safeguarding.

212 The Government has committed that statutory guidance will contain provisions for the integrated care partnership's integrated care strategy to consider child health and wellbeing outcomes and the integration of children's services.

213 The Act also requires the Secretary of State to publish a report by July 2023 that will describe the Government's policy on information sharing, by or with public authorities, in relation to the safeguarding of children. It will include an explanation of the government's policy on a consistent identifier for children. It will also include the government's approach and actions to implement the policy set out in the report.

Provision of Social Care Services: financial assistance

214 The Health and Social Care Act 2008 (the 2008 Act) 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.

215 Section 150 of the 2008 Act and the Health and Social Care (Financial Assistance) Regulations 2009 (S.I. 2009/649) 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 funded via integrated care boards or local authorities.

216 Section 67167 seeks to address this by making changes to sections 149-156 of the 2008 Act, 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.

217 These provisions do not amend the powers in these sections of the 2008 Act 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 is also not changed.

Professional Regulation

218 The powers provided through this Act 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.

219 Section 60 of the Health Act 1999 provides powers to make changes to the professional regulatory landscape through secondary legislation. This enables the regulation of new professions, the establishment of new regulatory bodies and the amendment of legislation in relation to nine health and care regulatory bodies which operate across the UK.

220 This section 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. Any use of the extended powers will be in collaboration with the devolved administrations. Orders may require the approval of the Scottish Parliament (where they concern professions brought into regulation after the Scotland Act 1998) or the Welsh Assembly (where the order concerns social care workers). The regulation of healthcare professions is a transferred matter in Northern Ireland (NI). UK Government will continue, as it does now, to seek the agreement of the Northern Ireland Executive when legislating on matters that effect regulation in its territory. These additional powers will widen the scope of section 60 and enable the Secretary of State to make additional changes.

221 The new powers will enable:

a. 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;

b. the removal of a profession from regulation where regulation is no longer required for the protection of the public;

c. the delegation of previously restricted functions to other regulatory bodies through legislation; and

d. the regulation of groups of workers concerned with health and care, whether or not they are generally regarded as a profession e.g. senior managers and leaders.

222 Secondary legislation made using the new powers would be subject to the existing provision in Schedule 3 and section 62 of the Health Act 1999, namely, consultation and the affirmative parliamentary procedure.

223 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.

224 The 2017 consultation *Promoting professionalism, reforming regulation* included questions relating to the provisions in the Act.[4] The Government response set out the proposals that were welcomed by key stakeholders, including professional organisations, regulatory bodies and employers.[5]

225 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.6 An independent review of the current make-up of the regulatory landscape, to review how it might be simplified to provide better public protection in a more efficient way, was carried out in 2021.

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4 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/655794/Regulatory_Reform_Consultation_Document.pdf

5 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf#:~:text=Promoting%20professionalism%2C%20reforming%20regulation%20set%20out%20high%20level,and%20more%20responsive%20to%20the%20needs%20of%20patients%2C

6 https://www.gov.uk/government/consultations/reducing-bureaucracy-in-the-health-and-social-care-system-call-for-evidence/outcome/busting-bureaucracy-empowering-frontline-staff-by-reducing-excess-bureaucracy-in-the-health-and-care-system-in-england

226 In March 2021, the UK Government published a consultation *Regulating healthcare professionals, protecting the public* that sets out proposed reforms to the legislation for professional regulators in four key areas: Governance and Operating Framework; Education and Training; Registration; and Fitness to Practise. The reforms will start with legislation that will bring physician associates and anaesthesia associates into regulation under the General Medical Council[7].

227 In 2022, the UK Government published a further consultation *Healthcare regulation: deciding when statutory regulation is appropriate*[8] on the criteria on deciding which professions are subject to statutory regulation.

228 This work, which builds on the work of the Law Commissions in their review of UK law relating to the regulation of healthcare professionals[9] paves the way for reforms that deliver a flexible and modern system of regulation for health and care professionals across the UK.

Medical Examiners

229 The Act amends the Coroners and Justice Act 2009 in England and Wales to set out a power for English and Welsh NHS bodies to appoint Medical Examiners. A duty is also imposed upon the Secretary of State and Welsh Ministers to ensure that enough medical examiners are appointed in the healthcare system in England and Wales respectively, 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.

230 The purpose of the amendment is to enable the introduction of a statutory scheme of medical examiners within the NHS rather than Local Authorities in England, and a range of Welsh NHS bodies rather than only local health boards in Wales. It is intended that, 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.

231 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.

Organ Tourism

232 Where it takes place, the purchase and sale of organs almost invariably leads to the exploitation of the organ donor. Existing legislation prevents commercial dealings in human material for transplantation in the UK, and overseas when a substantial part of the offence takes place in the UK. It also covers cases where a UK national arranges or facilitates the travel of the organ donor who is exploited in any part of the world. However, there was concern that

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[7] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978833/Regulating_healthcare_professionals__protecting_the_public.pdf

[8] Healthcare regulation: deciding when statutory regulation is appropriate - GOV.UK (www.gov.uk)

[9] https://www.lawcom.gov.uk/project/regulation-of-health-and-social-care-professionals/

legislation did not cover all scenarios in which a person from the UK might engage in the purchase and sale of organs, as there may be commercial dealings which involve UK nationals or residents but where no part of that dealing takes place here and where the UK national is not involved in the travel of the donor.

233 Section 170 provides for the criminalisation of the purchase or sale of organs outside the United Kingdom by extending the jurisdiction of offences described in section 32(1) of the Human Tissue Act 2004 and section 20(1) of the Human Tissue (Scotland) Act 2006 when they relate to human organs. These offences cover the purchase of organs, the supply of organs in exchange for payment, and the initiation or negotiation of any such arrangement.

234 The Human Tissue Act 2004 makes it a criminal offence to remove or store, for the purposes of transplantation, or to transplant, an organ without appropriate consent (section 5, read with section 1 and Schedule 1). It also makes it an offence to pay, or offer to pay, for an organ and to make arrangements for organ purchases (section 32(1)). Section 33 prohibits the removal and use of transplantable material from a living donor unless the requirements of regulations made under that section are met. These offences apply to those who carry out illicit removals and transplants (section 5) and those who make the arrangements for payment (section 32). They do not target the recipient of the transplanted material as such.

235 For England and Wales, the Modern Slavery Act 2015 covers cases where a UK citizen arranges or facilitates the travel of the organ donor who is exploited, in any part of the world. Section 2 prohibits UK nationals from arranging or facilitating the travel of a donor, with a view to their being exploited (which includes the commission, by him or her or another person, of what would be an offence in this country under section 32 or 33 of the Human Tissue Act 2004), while knowing, or being in a position where they ought to have known, that another person is likely to exploit the donor. The Human Trafficking and Exploitation (Scotland) Act 2015 and the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) (Northern Ireland) Act 2015 make similar provision for those territories.

Human Fertilisation and Embryology: Storage of Gametes and Embryos

236 Fertility preservation is increasingly possible through the freezing of gametes (eggs and sperm) and embryos. This allows fertility patients to keep their gametes or embryos in storage until they are ready to undergo treatment at a later date. The Human Fertilisation and Embryology Act 1990 (the "1990 Act"), as amended by the Human Fertilisation and Embryology Act 2008 (the "2008 Act"), sets the maximum storage limit for frozen gametes and embryos, which prior to the changes made by this Act was set at 10 years. In exceptional circumstances, those who are deemed to be "prematurely infertile", could store their gametes and embryos for longer – up to a maximum of 55 years. This was permitted through the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (the "2009 Regulations"). The provisions governing storage are set out in section 14 of the 1990 Act, and the requirements in relation to consent to storage are set out in Schedule 3 to that Act.

237 In February 2020 the Government launched a public consultation to test whether there was a case for changing the above storage limits, as fertility patients, the fertility sector, and fertility charities argued the current limit no longer functions to serve modern society. Such groups argued the maximum storage limit should be increased from the current 10 year limit to maximise reproductive choice for all, including for those who wish to freeze their gametes or embryos for social (non-medical) reasons, for example because they wish to start a family later in life.

238 The consultation ran from the 11 February 2020 until the 5 May 2020. In September 2021, following careful analysis of all submissions, the Government published its response to the consultation. The Government announced that the maximum storage limit for gametes and embryos would be increased from the current 10-year limit, to 10-year renewable periods up to a maximum of 55 years for all, regardless of medical need. The policy announcement by the Government on the 6 September 2021 was welcomed by key stakeholders, including fertility patients, charities, professional organisations, and the Human Fertilisation and Embryology Authority, the sector regulator.

239 These sections amend the 1990 Act to implement the above policy and increase the maximum storage period to 55 years for all. Patients will be required to renew their consent to storage every ten years. These changes will allow everyone, irrespective of medical need, to store their gametes or embryos for longer and therefore to make unpressurised decisions about when to start a family.

240 Embryos that are to be stored for the purposes of research and training will be limited to a maximum of 10 years, as is the case currently. This is because a 10-year storage period was judged to be sufficient for researchers to get approval for their proposals, to secure their research licences from the regulator, and for the projects using human embryos to be completed. The 1990 Act limits the length of time that human embryos can be used in research to a maximum of 14 days beginning the day on which the process of creating the embryo began or until appearance of the primitive streak, whichever comes first.

241 The sections also amend the 1990 Act to specify a scheme for the storage of donated gametes, embryos created from donated gamete(s), and donated embryos. In all these instances the donor(s) will be able stipulate the length of time that their donated materials can be stored and used for, up to the maximum of 55 years. Donors will not need to be contacted every 10-years to renew their consent in instances where they specify a storage limit longer than 10-years, however they will be able to contact the facility storing their material(s) and can withdraw their consent at any time, until the point of treatment. This is to enable donors to consider and set out how long their gametes or embryos are stored and used for; if they wish to avoid large age gaps between themselves and any donor-conceived children, they can do so.

242 The sections will also amend the 1990 Act to extend the provisions in relation to posthumous storage of gametes and embryos, where a person wishes to enable their partner to use their gametes or embryos made with their gametes after the person’s death. Under the 1990 Act, posthumous storage is already possible where a gamete provider gives consent to this. The consent requirement will remain. In addition, where a person who has given consent to posthumous use of their gametes or embryos dies, their storage period will automatically be renewed for a further 10 years from the date of their death. The living partner will need to provide a death certificate to the clinic to validate the extension; however, the death certificate does not need to be provided immediately and the extension can be applied retrospectively from the date of death by facilities. This change aims to provide the living partner with sufficient time to grieve, undertake counselling, and make unpressurised decisions about whether to undergo fertility treatment or not.

243 The sections in Part 2 also set out the transitional arrangements. The new provisions came into force on the 1 July 2022. The fertility sector, the regulator, and patients will have 2 years, until the 1 July 2024, to comply with the new requirements and to settle the status of any doubtful storage cases.

Advertising of less healthy food and drink

244 Obesity is one of the greatest long-term health challenges this country faces. Around two-thirds (63%) of adults are above a healthy weight and of these, half are living with obesity. The latest NCMP data from 2020/21 showed that around 40% of children leaving primary school in England were living with overweight or obesity, with 1 in 4 living with obesity[10]. 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 mental health.

245 In July 2020, the Government published its 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.

246 The intention of this Act is to reduce children's exposure to the advertising of less healthy food and drink products on TV and online. This Act introduces 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, from 1 January 2023. The Secretary of State has the power to delay the implementation date for the restrictions, should this be deemed necessary. All On Demand Programme Services (ODPS) under the jurisdiction of the UK, and therefore regulated by OFCOM, are included in the TV watershed. Other ODPS will be subject to the online prohibition because they are not defined in the Communications Act 2003, so are considered as "internet services".

247 This Act amends the Communications Act 2003[11] to enable OFCOM to introduce restrictions prohibiting advertising of less healthy food or drink between the hours of 5.30 a.m. and 9 p.m. on broadcast TV, and on ODPS[12] that are subject to Part 4A of the Communications Act 2003. This Act also introduces a prohibition of paid-for high fat, sugar and salt (HFSS) advertising online by inserting a new section into the Communications Act 2003 after Part 4B.

248 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.

249 OFCOM will be appointed as the appropriate regulatory authority. OFCOM will receive ￼￼, design statutory guidance and request information to help draft the guidance. 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)￼, design statutory guidance and request information to help draft the guidance. 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) to appoint a day-to-day regulator to carry out

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[10] NHS Digital (2021). National Child Measurement Programme 2020/21

[11] "Communications Act 2003 - Legislation.gov.uk". https://www.legislation.gov.uk/ukpga/2003/21/contents. Accessed 21 May. 2021.

[12] 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.
NHS Digital (2021). National Child Measurement Programme 2020/21.

frontline regulation, design statutory guidance and request information to help draft the guidance. 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).

250 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.

251 Prior to this Act, advertising on the internet was not subject to statutory regulation.

Hospital Food Standards

252 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.

253 The Independent Review of NHS Hospital Food[13] - 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
- Food safety
- Facilities
- Technology
- Enforcing standards
- Sustainability and waste

254 As well as recommendations on the above areas, the Hospital Food Review recommended 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.

255 This Act amends section 20 of the Health and Social Care Act 2008 to provide the Secretary of State for Health and Social Care with powers to make regulations imposing requirements relating to food or drink provided or sold to patients, staff, visitors or anyone else on hospital premises in England. 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.

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

257 Any regulations made under the provisions of this Act will be enforced by the Care Quality Commission (CQC) pursuant to their existing statutory powers of enforcement under the

[13] Report of the Independent Review of NHS Hospital Food, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/929234/independent-review-of-nhs-hospital-food-report.pdf

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 which are providers of regulated activities as defined in Section 8 of the Health and Social Care Act 2008. The section will not therefore apply to premises that are not within its regulatory remit.

Food information for consumers: power to amend retained EU law

258 Existing EU regulations were converted into domestic law by the European Union (Withdrawal) Act 2018. This Act enables technical changes to be made to food labelling and presentation requirements to reflect the United Kingdom's withdrawal from the EU.

259 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 European Union (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 Act provides the Secretary of State and Ministers of Scotland and Wales with powers to amend and modify retained Regulation (EU) No. 1169/2011 using secondary legislation, via an affirmative process. This section therefore allows the Government (and/or, where appropriate, a devolved authority) to make regulations to implement any new policies regarding food information and labelling.

260 The intention of the power is to broaden the reach of 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. This section 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.

261 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 to make healthier choices. If consultations indicate that changes to food and drink labelling and/or presentation are required, this provision will enable Ministers to introduce these policies, while 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.

Water Fluoridation

262 Research shows that water fluoridation is an effective public health intervention to improve oral health for both children and adults and reduces oral health inequalities. Around 10% of the population of England currently receive fluoridated water. If all 5-year-olds with drinking water with less than 0.2 milligrams per litre of fluoride instead received at least 0.7 milligrams of fluoride per litre then the number experiencing caries would reduce by up to 28% and the number of hospital admissions for tooth extractions in children and young people would reduce by up to 68%.

263 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.

264 In light of these challenges, the purpose of the sections within the Act that relate to water fluoridation is to give the 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.

Children's Palliative Care

265 Where there are disagreements about a child's treatment between those with parental responsibility and treating clinicians, or between different doctors, the court is asked to decide based on the child's best interests. Making such a declaration would be under the court's inherent jurisdiction, or the Children Act 1989. The views of the parents will be very important, but it is the child's best interests that are paramount, not the rights of those with parental responsibility.

266 Cases where there is a dispute between parents and clinicians over a child's care are extremely distressing for all involved. Getting the process right from the start through good communication and careful handling is the most important way to avoid or manage disputes.

267 The Act requires the Secretary of State to carry out a review of the causes of disputes between persons with parental responsibility for a critically ill child and the persons responsible for that child's treatment and care. This independent review will provide the Government with strong, evidence-based recommendations to support the creation of healthcare environments that foster good, collaborative relationships between parents and healthcare staff.

Permitted locations for abortion treatment

268 Section 178 amends the Abortion Act 1967 to make provision for early medical termination of pregnancy and applies to both England and Wales.

269 The amendment provides for the medication for early medical abortion to be taken in the home of the pregnant woman where the pregnancy has not exceeded 10 weeks, and permits registered medical practitioners to prescribe the medication for early medical abortion from their homes.

270 The amendment maintains the provision made by the temporary approval for at-home early medical abortion following a telephone or video consultation with a clinician, which was adopted in March 2020 in response to the COVID-19 pandemic.

Cosmetic Regulation

271 The current regulatory framework places few restrictions on who may perform non-surgical cosmetic interventions. There is also a lack of nationally recognised requirements or standards covering the education, training and qualifications required for the administration of these treatments. There is also no assurance that the premises in which non-surgical cosmetic interventions are carried out meet hygiene standards, or that individuals carrying out procedures have appropriate indemnity and insurance arrangements in place.

272 This amendment to the Health and Care Act will grant the Secretary of State a delegated power to introduce a licensing scheme for non-surgical cosmetic procedures and prohibit

carrying out these procedures without a licence or outside of licensed premises. Regulations made using these powers will be subject to the affirmative parliamentary procedure.

273 Both the personal licence and the premises licence will be issued by Local Authorities, which may also attach conditions to such licences.

274 The regulations may create offences related to: (i) a breach of the prohibition in the section (ii)a breach of conditions related to the personal licence or the premises licence, and (iii) the provision of false or misleading information to a local authority in connection with these licences. Such an offence would be punishable on summary conviction with a fine.

275 The details and scope of these regulations (including what specific procedures require a licence and the size of any fines) will be the product of an extensive engagement exercise and the section requires the regulations to be subject to a public consultation.

Mandatory training for learning disabilities and autism

276 The Learning from lives and deaths – People with a learning disability and autistic people (LeDeR) programme continues to find that people with learning disabilities and autistic people experience inequalities in access to health services. The second annual LeDeR report (2017), found that for a significant proportion of the deaths reviewed, the individual's health was affected by factors that were avoidable, with a lack of awareness of the needs of people with learning disabilities and autism among health and social care providers. The report recommended the introduction of mandatory training for all staff, delivered in conjunction with people with lived experience of learning disabilities.

277 In "Right to be heard" published in 2019, the government set out its intention to amend the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations"), to require all NHS and social care providers who carry out regulated activities to ensure that their staff have achieved the learning outcomes in respect of learning disabilities and autism relevant to their role. The CQC is responsible for monitoring compliance with the 2014 Regulations.

278 The policy intention of the Department of Health and Social Care is to make an explicit requirement in legislation for all health and social care employees who perform CQC regulated activities to undertake training on learning disability and autism appropriate to their role.

279 The Act introduces a duty in the Health and Social Care Act 2008 (HSCA 2008) on the Secretary of State to make regulations to require all health and social care providers who carry out regulated activities to ensure that their staff, who are employed for the provision of a regulated activity, receive specific training appropriate to their role on learning disability and autism.

280 The Act also introduces a duty on the Secretary of State to produce a Code of Practice (CoP) which will provide guidance about the nature of the training including the content, delivery and the ongoing evaluation of the training. The Government must consult on the CoP and lay a copy of the draft code before Parliament prior to publication.

281 The Act includes a provision which means that from commencement of the section, the 2014 Regulations and HSCA 2008 are to be read as including a requirement for all health and social care providers who carry out regulated activities to ensure that their staff receive specific training on learning disabilities and autism appropriate to their role.

282 The amendments are designed to operate within the existing framework of the HSCA 2008. Section 20 (1) of the HSCA 2008 requires the Secretary of State, by way of regulations, to

secure that services provided through regulated activities cause no avoidable harm to recipients. Section 20(2) provides that the Secretary of State may use regulations to impose any other requirement in relation to such regulated activities, particularly to ensure service quality and to secure the health, safety and welfare of service recipients. Section 20(3) provides a non-exhaustive list of what may be addressed by those regulations, including provision about the management and training of staff undertaking regulated activities.

283 Section 21 contains a specific provision relating to infections acquired in health care settings. If regulations are made under section 20 which contain requirements relating to the prevention or control of health care associated infections, the Secretary of State must produce a CoP about compliance with these requirements. The Act adds a new section 21A which sets out provision for a CoP relating to mandatory learning disability and autism training. Section 22 contains provisions which outline the consultation requirements for the CoP required under section 21. The Act will expand section 22 to cover both CoPs.

284 Section 23 provides that the CQC must issue guidance about the requirements of regulations made under section 20, other than requirements which relate to the prevention or control of health care associated infections (these are covered by the CoP provisions in section 21). Section 24 contains provisions outlining the consultation procedures for the guidance produced under section 23.

285 Section 25 sets out the circumstances in which the CoP under section 21 and guidance under section 23 may be taken into account in relation to decisions or orders under the HSCA 2008.

286 The 2014 Regulations are the regulations made under (amongst others) section 20 of the HSCA 2008 and set out the list of activities which are regulated by the CQC and the requirements which apply in relation to the way these activities are carried out.

287 Regulation 18 of the 2014 Regulations currently provides that “Persons employed by the service provider in the provision of a regulated activity must receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform…”.

288 Regulation 21 provides a general overarching guidance provision which requires regulated persons to take into account any guidance when complying with requirements in regulations, and in the case of regulation 12 (as it applies to health care associated infections), take into account the CoP issued by the Secretary of State under section 21 of the 2008 Act.

Territorial extent and application

289 Section 185 sets out the territorial extent of the Act, which describes the jurisdictions in which the Act will form part of the law. The extent of the Act can be different from its application and application is about where an Act produces a practical effect.

290 Largely the provisions in the Act extend to England and Wales only and apply to England, as health is largely a matter for devolved competence.

291 There are some provisions in the Act which extend UK-wide. A small number of these provisions will also apply UK-wide. Sections 140 to 143 and 152 to 155 (offences relating to virginity testing and hymenoplasty: Scotland) extend and apply to Scotland only. Sections 144 to 147 and 156 to 159 (offences relating to virginity testing and hymenoplasty: Northern Ireland) extend and apply to Northern Ireland only. An amendment, repeal or revocation made by this Act has the same extent as the provision amended, repealed or revoked.

292 See the table in the Annex for a summary of the position regarding territorial extent and application in the United Kingdom.

Commentary on provisions of the Act

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

NHS England

Section 1: NHS Commissioning Board renamed NHS England

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

Schedule 1: Renaming of NHS Commissioning Board

294 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" and other consequential name changes are made to specified primary legislation including some Welsh language text.

Section 2: Power to Require Commissioning of Specialised Services

295 Section 2 amends section 3B of the NHS Act 2006. This section 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, now, integrated care boards)– for example, patients with rare cancers, genetic disorders or complex medical or surgical conditions.

296 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 to commission it whether or not NHS England commissions the service itself or arranges for another body to commission the service under sections 13YB or 65Z5 of the NHS Act 2006.

297 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.

298 Subsection (4) requires the Secretary of State to explain to NHS England their reasoning, if he refuses a request from NHS England to revoke provisions made in regulations that prescribe services or facilities which NHS England must commission.

Section 3: Spending on Mental Health

299 Section 3 inserts new section 12F into the NHS Act 2006

300 New section 12F sets out a requirement for the Secretary of State to publish and lay before Parliament each financial year a document setting out whether the Secretary of State expects there to be an increase, in comparison to the previous financial year, in (i) the amount of expenditure incurred by NHS England and integrated care boards (taken together) in relation to mental health and (ii) the proportion of the expenditure incurred by NHS England and integrated care boards (taken together) that relates to mental health, and provide an explanation.

301 New section 12F(2) commits the Secretary of State to publish and lay the documents before the start of the financial year to which it relates.

302 Sub-section(3) inserts a new subsection (2B) into section 13U (annual report) of the NHS Act 2006, which requires NHS England to set out in their annual report a) the amount of expenditure incurred by NHS England and integrated care boards during the year (taken together) in relation to mental health; and b) a calculation of the proportion of the expenditure incurred by NHS England and integrated care boards during the year (taken together) that relates to mental health; and to c) provide an explanation of both.

Section 4: NHS England Mandate: general

303 Section 4 amends sections 13A 13B, 13T and 13U of the NHS Act 2006. Subsections (2)(a) and (b) remove 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.

304 Section 4(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.

305 Section 4(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.

306 Section 4(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.

307 Section 4(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.

308 Section 4(4) amends section 13T(3) and 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.

309 Section 4(5) substitutes paragraph (a) of 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.

Section 5: NHS England mandate: cancer outcome targets

310 Section 55 adds a further requirement to section 13A of the NHS Act 2006, relating to the content of the mandate. Specifically, it requires the Secretary of State to include objectives relating to cancer outcomes in the mandate.

311 Section 55(2) inserts a new subsection (2A) in section 13A, providing that the mandate must include objectives relating to outcomes for cancer patients. It further sets out that these objectives should be treated by NHS England as having priority over any other objectives included in the mandate that relate specifically to cancer.

Section 6: Duties as to reducing inequalities

312 Section 6 amends section 13G of the NHS Act 2006 to make it clear that NHS England's duty in relation to the reduction of inequalities in access to health services covers people before they are patients. It also makes it explicit that the duty to have regard to the need to reduce inequalities in outcomes for patients covers outcomes described in section 13E(3), such as the quality of experience undergone by patient.

Section 7: Duties in respect of research: business plan and annual report etc

313 This section amends the NHS Act 2006 to make further provisions relating to the research duty of NHS England. This section clarifies that NHS England's duty to promote research in the exercise of its function includes doing so by facilitating research. Section 40 in the Act similarly amends the wording of the research duty of the Secretary of State. Section 25 creates a corresponding research duty on integrated care boards.

314 The section also amends the existing provisions in the NHS Act 2006 for NHS England to publish a business plan and annual report so that they must include an explanation of how NHS England proposes to discharge or has discharged, respectively, its duty to facilitate or otherwise promote research.

Section 8: NHS England: Wider effect of Decisions

315 *Duty to have regard to effect of decisions* – this provision, which is inserted into the NHS Act 2006 as the new section 13NA, sets out a new duty for NHS England. A similar new duty also applies to integrated care boards (new section 14Z43), NHS Trusts in England (new section 26A) and NHS Foundation Trusts (new section 63A).

316 This duty has been described operationally as the "triple aim" duty.

317 Section 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 (paragraph (a)), the quality of services provided or arranged by relevant bodies (paragraph (b)) and the efficiency and sustainability of resources used by the relevant bodies (paragraph (c)).

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

319 Section 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. Under paragraphs (b) and (c), it also specifies that when complying with the Triple Aim duty, NHS England must consider inequalities in health and well-being and the benefits of services when considering the effects of their decisions on the areas in sections 13NA(1)(a) and (b).

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

321 Section 13NB gives NHS England a power to publish guidance on the discharge of the Triple Aim duty by NHS England, integrated care boards, NHS Trusts and NHS Foundation Trusts and requires NHS England to consult those who they view as appropriate when producing or revising the guidance.

Section 9: Duties in relation to climate change etc.

322 This section introduces a new duty on NHS England that requires it to have regard to how it can contribute to the achievement of the government's legislative targets regarding the environment and climate change. These are specified as: the target set under section 1 of the Climate Change Act 2008 (the Net Zero emissions targets, currently set for 2050) and the targets set under section 5 of the Environment Act 2021, which pertain to such matters as air quality, water quality and species abundance (among others). In addition, the duty requires NHS England to have regard to how it may support efforts to adapt to the predicted impacts of climate change as set out in the reports brought forward under section 56 of the Climate Change Act 2008. The duty applies when NHS England is exercising any of its functions. Section 13ND gives NHS England a permissive power to issue guidance on the climate change duties placed upon it, Trusts, Foundation Trusts and integrated care boards, and how those duties are to be discharged. Section 10: Public involvement and consultation: carers and representatives

323 This section amends section 13Q of the NHS Act 2006, which requires NHS England to involve individuals to whom health services are provided when exercising its commissioning functions. Following this amendment to subsection (2), NHS England is required to also involve carers and representatives of those individuals to whom health services are provided when exercising its commissioning functions. The term "carer" is broad in order to ensure it captures all groups of carers, including young carers and parent carers who provide care, unpaid, for a friend or family member who has needs for example arising from a disability, impairment or long term health condition.

Section 11: Information about inequalities

324 Section 11 inserts section 13SA into the NHS Act 2006. This requires NHS England to publish a statement describing the powers that certain NHS bodies have to collect, analyse and publish information relating to inequalities in accessing health services and in respect to the outcomes achieved for them by the provision of health services. The statement must also set out NHS England's view on how those powers should be exercised. The relevant bodies are integrated care boards, English NHS trusts, and NHS foundation trusts. The annual reports for the relevant bodies will need to state how far the functions have been exercised consistently with those views.

Section 12: Support and Assistance by NHS England

325 This section inserts a new section 13YA into the NHS Act 2006. 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) gives NHS England the power to give assistance or support to any person exercising functions in relation to the health service. (similar to the Secretary of State's power in section 254A of the NHS Act 2006).

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

327 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 integrated care boards.

328 Subsection (4) gives NHS England the ability to set the terms on which assistance or support under this section is provided based on what it considers appropriate.

Section 13: Exercise of functions relating to provision of services

329 This section inserts section13YB into the NHS Act 2006. It allows NHS England to direct an integrated care board to exercise any of NHS England's relevant functions. This is an alternative to entering into section 65Z5 arrangements to allow NHS England to delegate relevant functions to integrated care boards.

330 Subsection (2) sets out the NHS England functions which integrated care boards can be directed to exercise:

- 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.

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

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

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

334 Subsection (8) requires NHS England to publish any directions 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)).

Section 14: Preparation of consolidated accounts for providers

335 This section 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 previously 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 are revoked as a result of the abolition of Monitor and the TDA.

336 Subsection (2) of section 65Z4 gives the Secretary of State the power 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. Under subsection (3) NHS England must send a copy of the consolidated accounts to the Secretary of State and the Comptroller and Auditor and General within such period as the Secretary of State may direct. The Secretary of State can direct that the accounts must be accompanied by any reports or information (sub-section 4).

337 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.

Section 15: Funding for service integration

338 This section makes amendments to sections 223B ("Funding of NHS England") and 223GA ("Expenditure on integration") of the NHS Act 2006 to make provision for a fund for the purposes of service integration, known as the Better Care Fund. Section 223B already 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 that a designated amount of the annual payment is to be used for purposes of service integration.

339 Subsection (2)(a) substitutes subsection (6) of section 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 previous requirement to specify this sum in the mandate to NHS England under section 13A.

340 New subsection (6)(b) of section 223B provides that the Secretary of State may direct NHS England as to how this sum should be used.

341 Subsection (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 section 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 section 223B.

342 Subsection (3)(a) substitutes section 223GA(1) and (2) to provide that where the Secretary of State has given NHS England a direction under section 223B(6)(a) about sums paid to it for service integration purposes, NHS England may direct integrated care boards 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.

343 Subsection (3)(c) omits subsection (7) of section 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.

344 "Service integration" means the integration of health services with health-related or social care services.

Section 16: Payments in respect of quality

345 This section repeals subsections (4) and (5) of 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 as set out under those subsections. Other subsections of section 223K remain in the NHS Act 2006 including the regulation-making power at subsection (6).

Section 17: Secondments to NHS England

346 This section inserts paragraph 9A in Schedule A1 to the NHS Act 2006 and amends section 272 of the NHS Act 2006 as a consequence. Subsection (3), 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 the list of NHS bodies (see paragraph 9A(4)) can be considered as employees of NHS England in respect of references to employees at paragraphs 9, 10 and 13 of Schedule A1. Under paragraph 9A(5), the Secretary of State may by regulations amend paragraph 9A to include other references to employees of NHS England in the Act within this provision as well as setting out further persons of a prescribed description who are seconded to NHS England. Such regulations are subject to the draft affirmative procedure.

Integrated Care Boards

Section 18: Role of Integrated Care Boards

347 *General functions of integrated care boards* - This section replaces section 1I of the NHSNHS Act 2006 and sets out that any integrated care board established under Chapter A3 of Part 2 of the NHS Act 2006 has the function of arranging for the provision of services for the purposes of the health service in England. The "health service" means the health service in England.

Section 19: Establishment of Integrated Care Boards

348 *Establishment of integrated care boards (including by re-purposing clinical commissioning groups).* This section inserts Chapter A3 into the NHS Act 2006. This Chapter includes new sections 14Z25 to 14Z28 which make provision for the abolition of CCGs and the establishment of integrated care boards; new section 14Z29 which concerns the publication of an integrated care board's constitution; and new section 14Z30 which concerns the management of conflicts of interest.

349 *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 of the NHS Act 2006.

350 *Process for establishing initial integrated care boards.* New section 14Z26 subsection (1) requires NHS England to publish a list of the initial 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 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. Subsection (5) states that nothing in this section prevents NHS England from establishing the first integrated care board in a case where the relevant clinical commissioning group or groups have failed within a reasonable period to make a proposal under subsection or limits the re-exercise of the power in section 14Z25. 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).

351 *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)).

352 *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. Transfer schemes in connection with the establishment of integrated care boards may transfer property, rights or liabilities from NHS England, an NHS trust, an NHS foundation trust or a Special Health Authority to the board. 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 where property, rights or liabilities can be transferred to NHS England or another integrated care board. Under subsection (5), NHS England is required to ensure that all property, rights and liabilities (except criminal liabilities) of CCGs are transferred to one integrated care board, if the CCG's area coincides with that integrated care board's area, or to one or more integrated care boards if the areas do not coincide. Rights and liabilities include rights and liabilities relating to contracts of employment. Subsection (7) contains a list of things a transfer scheme may do, including 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.

353 *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.

354 *Register of interests and management of conflicts of interests.* New section 14Z30 subsection (1) requires each integrated care board to maintain and publish (or make arrangements for access to) 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.

355 Section 19 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

356 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". Paragraph (4) sets out that the constitution must specify that an integrated care board must not appoint a person as member of an integrated care board if that appointment could reasonably be regarded as undermining the independence of the NHS because of their involvement in the private health sector or otherwise.

357 Under paragraph (5), the chair of the integrated care board will be appointed by NHS England, with the approval of the Secretary of State. Under paragraph (6), 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.

358 Under paragraph (7), 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.

359 Under paragraph (8), 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)).

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

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

361 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)).

362 Under subsection (5) the descriptions of trusts or other persons that may be prescribed for the purposes of sub-paragraph (2)(a) or (b) may, in particular, be framed by reference to the nature of the services that they provide or the proportion of their services that are provided within the integrated care board's area.

363 Under subsection (6), the chair must exercise the approval function mentioned in sub-paragraph (1)(b) with a view to ensuring that at least one of the ordinary members has knowledge and experience in connection with services relating to the prevention, diagnosis and treatment of mental illness.

364 Under paragraph (9), the constitution may include further details concerning the membership of the integrated care board such as how members are to be appointed and the conditions of membership (e.g. tenure, remuneration, eligibility for re-appointment). Under paragraph (10), further requirements in relation to the constitution may be set out in regulations, which the integrated care board must adhere to.

365 Under paragraph (11), 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, this would allow the delegating of 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. Sub-paragraph (4) prohibits the chair from approving or appointing someone as a member of any such committee or sub-committee if the chair considers that the appointment could reasonably be regarded as undermining the independence of the health service because of the candidate's involvement with the private healthcare sector or otherwise.

366 Under paragraph (12), the constitution must also detail the procedure the integrated care board will follow when making decisions and how the board will ensure that decisions are made transparently. Paragraph (13) requires the constitution to include detail about how it will maintain registers of interests (as required under section 14Z30) and how any conflicts of interest will be identified and managed. The constitution should also detail how the integrated care board will fulfil its duties to involve or consult the public as required under section 14Z45(2) (under paragraph (14)) including a statement of the principles to be followed in implementing such arrangements).

367 Under paragraph (15), the constitution must detail the process for how the constitution can be amended. This must 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. The intention is for NHS England to issue a model constitution to assist integrated care boards in developing their own. Paragraph (16) sets out that the constitution may make further provision to those matters already listed in Part 1.

Part 2

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

369 Paragraph (17) sets out that an integrated care board is a body corporate, which means it has its own legal rights and responsibilities; and it, and its property, is not to be considered as an agent, or property, of the Crown.

Staff

370 Under paragraph (18), 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.

371 Under paragraph (19), an integrated care board may arrange for individuals to be seconded to it 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 as covered by paragraphs 11 and 18 of the Schedule (sub-paragraph (3)). For the purposes of paragraph 7(2) (the requirement for the chief executive to be an employee) 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 English NHS Trust, an NHS Foundation Trust, an English Special Health Authority, the Care Quality Commissioning, 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 the paragraph to provide that other references in the NHS Act 2006 to an employee of an integrated care board also includes persons seconded and

also may amend the description of persons who covered by the paragraphs (sub-paragraph (5)). Such regulations would be subject to the draft affirmative procedure.

Additional powers in respect of payment of allowances

372 Under paragraph (20), an integrated care board may pay appropriate allowances to members of committees or sub-committees of the board who are not a member of the integrated care board, should it consider this to be appropriate.

Externally financed development agreements

373 Under paragraph (21), 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 certified in writing by the Secretary of State (sub-paragraph (2)). The Secretary of State may certify this if the purpose of the agreement is the provision of services or facilities in connection with the 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

374 Under paragraph (22), 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

375 Under paragraph (23) 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

376 Where used, the integrated care board's seal must be authenticated by the signature of an authorised person (paragraph (24)).

Section 20: People for whom integrated care boards have responsibility

377 Subsection (2) inserts section 14Z31 in the NHS Act 2006. Section 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 integrated care board responsibility will continue to be in relation to GP registration to ensure operational continuity. Section 14Z31(2) ensures that, at a minimum, under the rules published by NHS England, an integrated care board 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 integrated care board, 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 section 14Z31(3), regulations may create exceptions to these rules. These regulations will be subject to the draft affirmative procedure.

378 Subsection 20(4) provides that 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 section 14Z31. Such regulations will be subject to the draft affirmative procedure.

Integrated Care Boards: Functions

Section 21: Commissioning hospital and other health services

379 This section amends section 3 of the NHS Act 2006 to require integrated care boards to commission hospital and other health services for those persons for whom the integrated care board is responsible to such extent as it considers necessary to meet the reasonable requirements of those people.

380 *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 to such extent as it considers necessary to meet the reasonable requirements of those persons for whom the integrated care board is responsible. Integrated care boards are responsible for those people specified in accordance with section 14Z31 and any other people who may be prescribed in regulations (subsection (2)). Subsection (3) ensures there is no duty to commission services or facilitate those which are already being commissioned by NHS England, and other integrated care boards. This ensures there is no duplication in the required commissioning arrangements. 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.

381 *Power of integrated care boards to commission certain health services.* New section 3A allows, but does not require, integrated care boards to arrange for the provision of such services or facilities that it considers appropriate 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.

Section 22: Commissioning primary care services etc.

382 This section 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.

383 This Schedule 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. 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.

384 Part 1 of this Schedule contains amendments made to the NHS Act 2006.

385 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) enable 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

386 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 section 14Z31 and any other people who may be prescribed in regulations). Regulations under section 82A may set out how primary medical services should be defined for the purposes of this Act. Such regulations would be subject to the negative procedure.

387 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.

388 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.

389 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.

390 New section 98B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under Part 4 (Medical Services) of NHS Act 2006.

Dental services

391 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 section 14Z31 and any other people who may be prescribed in regulations). Regulations under section 98C may set out how primary dental services should be defined for the purposes of this Act. Such regulations would be subject to the negative procedure

392 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.

393 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.

394 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.

395 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.

396 New section 114B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under Part 5 (Dental Services) of NHS Act 2006.

Ophthalmic services

397 Section 115 is amended by paragraph 29 of Schedule 3. It 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 section 14Z31 and any other people who may be prescribed in regulations). Regulations under section 114C may set out how primary ophthalmic services should be defined for the purposes of this Act. Such regulations would be subject to the negative procedure.

398 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.

399 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.

400 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.

401 New section 125B allows NHS England to direct an integrated care board about the exercise by it of any of its functions under Part 6 (Ophthalmic Services) of NHS Act 2006.

Pharmaceutical services

402 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 Part 7 (Pharmaceutical Services and Local Pharmaceutical Services) of the NHS Act 2006.

403 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 section 65Z5 (by agreement) or section 13YB(2)(b)(iv) (by direction).

Part 2 – Consequential amendments

404 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, Health and Social Care (Community Health and Standards) Act 2003, Health Act 2006, NHS Act 2006, National Health Service (Wales) Act 2006, Health Act 2009, and the Domestic Abuse Act 2021.*

Section 23: Transfer schemes in connection with transfer of primary care functions

405 This section 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 primacy care functions from NHS England to an integrated care board.

406 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 and allows for provision to be made which is 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.

Section 24: Commissioning arrangements: conferral of discretions

407 This section amends section 12ZA of the NHS Act 2006. Section 12ZA makes provision about commissioning arrangements made by NHS England and CCGs (now integrated care boards). Subsection (2A) states that arrangements may confer discretions on a person with whom they are made so, for example, it could allow persons with whom NHS England and integrated care boards have entered into commissioning arrangements to determine the means by which services will be delivered.

Section 25: General functions

408 *Duty to promote the NHS Constitution*. Section 14Z32 imposes a duty upon each integrated care board 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 the NHS Constitution 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 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.

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

410 *Duty as to improvement in quality of services.* 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 section 14Z34(3) integrated care boards should, in particular, look to continuously improve effectiveness of services, safety of services and patient experience.

411 *Duties as to reducing inequalities*. Section 14Z35 sets out that integrated care boards must, in the exercise of their functions, have regard to the need to reduce inequalities between persons in relation to their ability to access health services and in the outcomes achieved from health services. Section 14Z35 (b) makes explicit that these outcomes for patients includes outcomes such as the quality of experience undergone by patients as described in section 14Z34(3).

412 *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. The reference to "carer" would include young carers and parent carers who provide care, unpaid, for a friend or family member who has needs, for example, arising from a disability, impairment or long-term health condition.

413 *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).

414 *Duty to obtain appropriate advice.* 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.

415 *Duty to promote innovation.* Section 14Z39 imposes a duty on integrated care boards, in the exercise of their functions, to promote innovation in the provision of health services including in making arrangements for the provision of health services.

416 *Duty in respect of research.* Section 14Z40 puts a duty on integrated care boards in respect of research. Each integrated care board must, in the exercise of its functions, facilitate or otherwise promote health research and the use of evidence obtained from research. The aim of this section is to further embed research in the health and care system.

417 In practice, each integrated care board could exercise its duty to facilitate or otherwise promote research and the use of evidence obtained from research by:

- considering research when exercising its commissioning functions, both in terms of ensuring that the services commissioned have been informed by the evidence obtained from research and in selecting providers who are research-active;
- encouraging its providers to be actively involved in the delivery of research and to provide services that are informed by evidence from research;
- having a dedicated research office/team providing support for research;
- articulating local research needs when assessing local needs, articulating plans for addressing these when preparing strategies and plans, and encouraging its partner organisations to play an active and collaborative role in pursuing these;
- having Board-level discussions on research activity, the use of the evidence from research, the research workforce, and research culture within the integrated care system; and/or
- where appropriate, exercising the duty to facilitate or otherwise promote research in conjunction with its power to conduct, commission or assist the conduct of research (paragraph 13(1) of Schedule 1 of the NHS Act 2006), for example by hosting or being a collaborating partner in research infrastructure.

418 *Duty to promote education and training*. 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, so as to assist the Secretary of State and Health Education England in the discharge of the duty under section 1F.

419 *Duty as to promoting integration*. Section 14Z42 requires integrated care boards to exercise their functions with a view to ensuring that health services are integrated with the provision of social care and health-related services 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.

420 *Duty to have regard to effect of decisions.* 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.

421 This duty has been described operationally as the "triple aim" duty.

422 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 (paragraph (a)), the quality of services provided or arranged by relevant bodies (paragraph (b)) and the efficiency and sustainability of resources used by the relevant bodies (paragraph (c)).

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

424 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. Under subsections (b) and (c), it also specifies that when complying with Triple Aim duty, integrated care boards must consider inequalities in health and well-being and the benefits obtained from services.

425 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.

426 *Duties as to climate change:* Section 14Z44 introduces a new duty on Integrated Care Boards that requires each integrated care board to have regard to how it can best support the achievement of the government’s legislative targets regarding the environment and climate change. These are specified as: the target set under Section 1 of the Climate Change Act (the Net Zero emissions targets, currently set for 2050) and the targets due to be set under Section 5 of the Environment Act, which pertain to such matters as air quality, water quality and species abundance (among others). In addition, the duty requires each integrated care board to have further regard to how it may support efforts to adapt to the predicted impacts of climate change as set out in reports brought forward under section 56 of the Climate Change Act. The duty applies when an integrated care board exercises all of its functions. Subsection (2) of the duty requires integrated care boards to have regard to any guidance issued by NHS England under section 13ND on how it is to discharge this duty.

427 *Public involvement and consultation by integrated care boards.* Section 14Z45 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 section 14Z45(2), arrangements must be made to secure the involvement of individuals and their carers and representatives 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 such an impact. Under section 14Z45(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.

428 *Joint exercise of functions with Local Health Boards*. Regulations may be made under section 14Z46(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. Such regulations would be subject to the negative procedure.

429 *Raising additional income.* Section 14Z47 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.

430 *Power to make grants.* Section 14Z48 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.

431 *Duty to keep experience of members under review.* Section 14Z49(a) requires an integrated care board to keep under review the skills, knowledge and experience that it considers, when taken together, necessary for the members of the board to have in order for the board to effectively carry out its functions. Section 14Z49(b) requires the board to take such steps as it considers necessary to address or mitigate the shortcoming that they identified. This could, for example, be through the membership or through taking expert advice.

432 *Responsibility for payments to providers.* Section 14Z50 (1) provides that NHS England may 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 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. 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).

433 *Guidance by NHS England.* Section 14Z51 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.

434 *Joint forward plans for integrated care board and its partners.* Section 14Z5214Z52 makes provision with regard to commissioning plans. Subsection (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 financial year to set out how they propose to exercise their functions over the next 5 years. In practice, it is expected that this plan will set out how an integrated care board will meet the health needs of its population and this will include primary, community and acute care. Under subsection (2((a) the joint forward plan for an integrated care board and its partners must describe the health services that the board proposes to commission over the period. Under subsection(2)(b), the plan must, in particular, explain how the integrated care board proposes to discharge each of its duties under sections 14Z34 to 14Z45 (general duties of integrated care boards) and sections 223GA to 223N (financial duties). These general duties sections cover: continuous improvement in the quality of services; reducing inequalities; promoting involvement of each patient; enabling patient choice; obtaining appropriate advice; promoting innovation; facilitating or otherwise promoting research and the use of evidence from research; promoting education and training; promoting integration, how it will fulfil its duty to have regard to the wider impact of decisions have regard to certain matters relating to the environment, including climate change; and ensure public involvement and consultation. Under subsection (2)(c), 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. Under subsection (2)(d), the forward plan must also set out any steps the integrated care board proposes to take to address the particular needs children and young persons under

the age of 25 and under subsection (2)(e) the steps it proposes to take to address the particular needs of victims of abuse.

435 Under subsections (3) and (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 under subsection (5). An integrated care board and its partner NHS trusts and NHS foundation trusts must have regard to the plan (subsection (6)).

436 *Revision of forward plans.* Under Section 14Z53, the forward 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. Under subsection (3), where the integrated care board revises the plan and the changes are not significant, it must publish a document setting out the changes and give a copy of that document to the integrated care partnership, each relevant health and wellbeing board and NHS England.

437 *Consultation about forward plans.* Under section 14Z54, when preparing a forward plan, or making a change it deems significant, the integrated care board must consult individuals for whom it has core responsibility for and any other persons they consider it appropriate to consult.

438 Under subsections (3) and (4), 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.

439 Under subsections (5) and (6), the Health and Wellbeing Board is required to respond with its opinion on the matter it is consulted upon and may also give its opinion to NHS England. Where a Health and Wellbeing board gives an opinion to NHS England, it must inform the integrated care board and its partner NHS trusts and foundations trusts. 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.

440 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.

441 *Opinion of Health and Wellbeing Boards on forward plan*. Section 14Z55 allows each Health and Wellbeing Board to provide NHS England with its opinion on whether an integrated care board's forward 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.

442 *Joint capital resource use plan for integrated care board and partners*. Section 14Z56 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 (and such a direction must be published (subsection (3)). The plan must be published

(subsection (4). Under subsection (5), the integrated care board and its partner NHS Trusts and Foundations Trusts 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) and the integrated care board and its partner NHS trusts and foundation trusts must have regard to such guidance (subsection (8)).

443 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.

444 Under section 14Z57, a plan published under section 14Z56 can be revised. Any revisions the integrated care board and its partner NHS trusts and foundation trusts consider significant must be published and a copy provided to NHS England, the integrated care partnership and each relevant Health and Wellbeing Board. Under subsection (3), where the revised plan does not contain significant changes, the integrated care board and its partner NHS trusts and foundation trusts must publish a document setting out the changes and give a copy of that document to the integrated care partnership, each relevant health and wellbeing board and NHS England.

445 *Annual report* Section 14Z58 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 proposes to discharge each of its duties under sections 14Z34 to 14Z45 facilitating or otherwise the use of from research. 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 use 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. Under subsection (4) the annual report must include a statement of the expenditure incurred by the integrated care board during the financial year that relates to mental health and an explanation of the statement and calculation. NHS England may give directions to integrated care boards as to the form and content of the report (subsection (5)). The integrated care board must also publish the annual report and give copies to NHS England by a date specified by NHS England (subsection (6)).

446 *Performance assessment of integrated care boards.* Section 14Z59 stipulates that NHS England must conduct a performance assessment of each integrated care board in respect of each financial year.

447 Under subsection (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 (section 14Z34), reducing inequalities (section 14Z35), obtaining appropriate advice (section 14Z38), having regard to effect of decisions (section 14Z43), public involvement and consultation (section 14Z45), financial duties (sections 223GB to 223N) and the duty to have regard to assessments and strategies (section 116B(1) of the Local Government and Public Involvement in Health Act 2007).

448 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 14Z51 or any guidance published by the Secretary of State (subsection (5)). NHS England must publish a report in respect of each financial year containing a summary of the results of each performance assessment conducted by NHS England in that year (subsection (6)).

449 *Power of NHS England to obtain information:* Under section 14Z60, NHS England may require an integrated care board to provide NHS England with any necessary documents or other information.

450 *Power to give directions to integrated care boards:* Section 14Z61 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. Subsection (2) provides that NHS England may direct an integrated care board to discharge those functions in a specified manner within a specified period.

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

- direct the integrated care board or chief executive of the integrated care board to ceases to perform 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.

452 Under section 14Z62, before giving directions under section 14Z61(5)(b) or (8)(b) NHS England must consult the integrated care board to which it is proposing to give the direction or to whose chief executive it is proposing to give the direction (subsection (1)). The integrated care board is required to cooperate with any chief executive who is directed to exercise its functions (subsection (2)).*Permitted disclosures of information:* Section 14Z63 stipulates that integrated care boards are permitted to disclose information obtained in the exercise of its functions in the circumstances listed in subsection (1).

453 *Interpretation:* Section 14Z64 defines the terms used in the chapter.

454 Subsection (3a) inserts subsection (1A) after subsection (1) of section 48 of the 2006 Act requiring partner NHS foundation trusts to share any information required by integrated care boards with them.

455 Subsection (3b) substitutes subsection (2) of section 48 of the 2006 Act requiring partner NHS foundation trusts to provide information in such form, and at such time or within such period, as may be specified by the person imposing the requirement.

456 Subsection (4a) converts the existing provision in paragraph 13 of Schedule 4 to sub-paragraph (1).

457 Subsection (4b) inserts sub-paragraph (2) in paragraph 13 of Schedule 4 requiring partner NHS trusts to share any information with its partner integrated care board that it requires and inserts subsection (3) in paragraph 13 of Schedule 4 which requires information in subsection (2) to be submitted in such form, and at such time or within such period, as may be specified by the integrated care board.

Integrated Care Partnerships

Section 26: Integrated Care Partnerships and Strategies

458 This section 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 and its integrated care strategy.

459 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.

460 Subsection (4) inserts new sections into the Local Government and Public Involvement in Health Act 2007 relating to integrated care partnerships and their strategies.

461 Section 116ZA(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 one member appointed by the integrated care board and one member appointed by each relevant local authority and any members appointed by the integrated care partnership itself. Under subsection (3), the integrated care partnership may determine its own procedures (including quorum).

462 Section 116ZB(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 the exercise of functions of either the integrated care board in the area, NHS England, or the relevant 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 to make arrangements. 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)). The strategy may also state how health-related services could be more closely integrated (subsection (5)).

463 Under subsection (6), the integrated care partnership must consider revising its integrated care plan whenever it receives a new joint strategic needs assessment. Under 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.

464 Section 26(5) of the Act inserts into section 116A of the Local Government and Public Involvement in Health Act 2007 a requirement for local authorities and their partner integrated care boards, in response to an integrated care strategy, to prepare a "joint local health and wellbeing strategy" that sets out how the local authorities, integrated care board and NHS England will meet the assessed needs in that area. "Assessed needs", in relation to the area of a local authority, means the needs assessed in relation to its area under section 116.

465 Section 26(6) of the Act substitutes section 116B and 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

Section 27: NHS England's financial responsibilities

466 This section substitutes sections 223C to 223E of the NHS Act 2006.

467 *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.

468 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.

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

470 *Financial duties of NHS England: controls on total resource use.* New 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, English NHS trusts and NHS foundation trusts taken together. Subsection (2) excludes transfers of resource between those bodies from the definition of resource use.

471 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.

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

473 *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 use 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.

Section 28: Expansion of NHS England's duties in respect of expenditure

474 This section enables new section 223C of the NHS Act 2006 (as substituted by section 27 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.

Section 29: Financial Responsibilities of integrated care boards and their partners

475 *Power to impose financial requirements on integrated care boards.* This section omits sections 223H to 223J (financial duties of clinical commissioning groups) of the NHS Act 2006 and inserts a number of new sections. New section 223GB 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. These requirements can be imposed on any integrated care boards specified, who must comply with them. Under subsection (3), NHS England must publish any directions issued under this section.

476 *Financial duties of integrated care boards: 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, by direction, 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.

477 *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.

478 *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.

479 *Financial duties of integrated care boards: use of resources.* Under new section 223M, 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.

480 *Financial duties of integrated care boards: additional controls on resource use.* New section 223N allows NHS England to give direction to an integrated care board and its partner NHS trusts and foundation trusts, to exercise their functions with a view to ensuring 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.

481 *Resources etc. relevant to sections 223D, 223E, or 223M.* New section 223O 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 sections 223D, 223E, or 223M.

Section 30: Expansion of financial duties of integrated care boards and their partners

482 Financial duties of integrated care boards etc: expenditure limits. This section, 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 expend 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.

Integrated Care System: reviews and further amendments

Section 31: Care Quality Commission reviews etc of Integrated Care System

483 This section amends Chapter 3 of Part 1 of the Health and Social Care Act 2008 (“the 2008 Act”) to place a duty on the Care Quality Commission (CQC) to review integrated care systems.

484 Subsection (2) inserts a new section 46B, into the 2008 Act.

a. Subsection (1) of new section 46B requires the CQC to (a) conduct reviews of the provision of “relevant health care” (defined as NHS care and public health) and adult social care within the area of each integrated care board; (b) assess the functioning of the system in relation to the provision of this care, and in particular, how the various bodies work together, including for example the role of the integrated care partnership; and (c) publish a report of this assessment.

b. Subsection (2) requires the Secretary of State to (a) set, and from time to time revise, objectives and priorities for the CQC in relation to assessments under the section and (b) inform the CQC of these. Subsection (3) requires that priorities set by the Secretary of State under subsection (2)(a) must include priorities relating to leadership, the integration of services and the quality and safety of services. Subsection (4) requires the CQC to (a) determine, and from time to time revise, indicators of quality for these assessments and (b) obtain the approval of the Secretary of State for these indicators. Subsection (5) allows the Secretary of State to direct the CQC to revise these indicators. Subsection (6) allows for different objectives, priorities and indicators for different cases.

c. Subsection (7)(a) requires the CQC to prepare, and from time to time revise, a statement on (i) the frequency of reviews and period to which the reviews relate, and (ii) the method of assessment and evaluation for these reviews. Subsection (7)(b) requires the CQC to obtain the approval of the Secretary of State for this statement. Subsection (8) allows the statement to make different provision regarding the frequency, period and method for different cases. Subsection (9) requires the CQC to consult NHS England and any other persons it considers appropriate before preparing or revising the statement. Subsection (10) allows the Secretary of State to direct the CQC to revise the statement.

d. Subsection (11) requires the CQC to publish (a) the objectives and priorities, (b) the indicators of quality, and (c) the statement on frequency and method.

e. Subsection (12) defines terms used in section 46B, with subsection (13) allowing for the definition of “relevant health care” to be amended by way of Regulations. Such regulations would be subject to the draft affirmative procedure.

485 Section 31(3) of the Act amends section 48 of the 2008 Act (special reviews) so that a review under section 46B is not a special review under section 48 of the 2008 Act.

486 Section 31(4) of the Act amends section 50 of the 2008 Act to add reviews under section 46B requiring CQC to take certain steps if it considers a local authority is failing to discharge any of its adult social care functions to an acceptable standard.

Section 32: Integrated Care System: further amendments

487 This section inserts Schedule 4 which makes minor and consequential amendments relating to integrated care boards.

Schedule 4: Integrated Care System: minor and consequential amendments

488 This Schedule makes minor and consequential amendments to do with integrated care systems.

Merger of NHS bodies etc.

Section 33: Abolition of Monitor and transfer of functions to NHS England

489 This section 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 section and related schedule fulfils the intention 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

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

Section 34: Exercise by NHS England of new regulatory functions

491 This section inserts a new section 13SB (Minimising conflicts between regulatory and other functions), in the NHS Act 2006. Section 13SB 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 13SB duty.

Section 35: Modification of standard license conditions

492 This section amends section 100 of the 2012 Act. Section 100 allows NHS England to modify standard licence conditions in all providers' licences or in licences of a particular description.

493 Section 100(1A) 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.

494 Subsection (3) makes consequential amendments to section 100.

495 Subsection (4) requires NHS England to include any assessment carried out under subsection (1A) in the notice given to providers and others.

Section 36: Abolition of NHS Trust Development Authority

496 This section fulfils the intention to merge the TDA into NHS England to form a single body by transferring the appropriate functions of the TDA. Subsection (1) abolishes 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).

497 Subsections (2)(b) and (2)(c) 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 subsections (3) and (4) makes consequential amendments that arise as a result of the abolition of the TDA.

Section 37: Merger of bodies: consequential amendment

498 This section makes consequential amendments to NHS England's general duties in the 2012 Act to reflect its new oversight role of NHS Trusts and Foundation Trusts.

Section 38: Transfer schemes in connection with abolished bodies

499 This section 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.

Section 39: Transfer schemes under section 38: taxation

500 This section 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 38, or anything done for the purposes of, or in relation to, a transfer under such a scheme.

501 The intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. Section 38 provides a power for the Treasury to vary any relevant tax in order to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise.

Secretary of State's functions

Section 40: Duties in respect of research

502 This section amends the NHS Act 2006 to clarify that the Secretary of State's duty to promote research, in exercising functions in relation to the health service, includes doing so by facilitating research. The section inserts the words "facilitate or otherwise" into the duty. Section 7 of the Act similarly amends the wording of the research duty of NHS England. Section 25 creates a corresponding research duty on integrated care boards.

Section 41: Report on assessing and meeting workforce needs

503 This section inserts a new Section 1GA into the NHS Act 2006.

504 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.

505 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.

Section 42: Arrangements for exercise of public health functions

506 This section 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.

Section 43: Power of direction: public health functions

507 This section introduces a new section 7B into the NHS Act 2006 and allows the Secretary of State 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) of NHS Act 2006 or certain functions under Schedule 1 to NHS Act 2006. Subsection (2) defines relevant bodies as NHS England and integrated care boards.

508 Subsection (3) of new section 7B provides that a direction may prohibit or restrict a relevant body from making delegation arrangements. 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.

509 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.

510 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.

511 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.

512 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.

513 New section 7B adds to existing powers whereby the Secretary of State can arrange for a range of other bodies to exercise public health functions (via section 7A of the NHS Act 2006).

Section 44: Power of Direction: investigation functions

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

515 Subsection (2) inserts a new section 7C (Power of direction: investigation functions) into the NHS Act 2006 which 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.

516 Subsections 7C(2) and 7C(3) provide that the direction may prohibit or restrict the body directed from making delegation arrangements in relation to a function covered by the direction. Subsection 7C(4) provides that the Secretary of State may make payments to NHS England or any other public body in respect of the exercise of those investigation functions. Subsection 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 13ZC of the NHS Act 2006 gives the Secretary of State a power to give directions to NHS England as to the exercise of its functions, as noted by subsection 7C(6).

517 Any directions made under subsections 7C(1) or (5) must be published by the Secretary of State as soon as is reasonably practicable. Should any rights be acquired, or liabilities incurred by NHS England or and other public body by virtue of section 7C, they are enforceable by or against it and no other person.

518 Subsection 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 NHS 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 NHS Act 2006 (the HSIB maternity investigations 2018).

519 Subsection (2) also inserts a new section 7D (transfer schemes in connection with a direction under section 7C) into the NHS Act 2006. Subsections (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.

520 Subsection (3) clarifies what may be transferred under the transfer scheme which includes property, rights and liabilities (including criminal liabilities).

521 7D subsections (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 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, and could offer certain protections of employment rights for transferred staff.

522 Subsection 2 of Section 44 of the Act also inserts a new section 7E (Transfer schemes under section 7D: taxation) 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.

523 The intention is that any transfer of assets, rights, or liabilities be tax neutral for the transferee and the transferor. This section includes a power for the Treasury to vary any relevant tax so if necessary it can be used to ensure that no taxes arise, and no changes to the tax position of either the transferee or transferor body arise.

Section 45: General power to direct NHS England

524 This section 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:

- Section 13ZC Secretary of State directions as to the exercise of NHS England functions;

- Section 13ZD Power to give directions: exceptions

- Section 13ZE Compliance with directions: significant failure

- Section 13ZF Secretary of State directions to provide information.

525 New section 13ZC gives the Secretary of State the power to direct NHS England as to the exercise of any of their functions. Any direction given to NHS England under this section by the Secretary of State must be made in writing, must include a statement that it is in the public interest and must be published as soon as reasonably practicable after it is given.

526 A direction under section 13ZC may include directing NHS England in relation to whether a power is to be exercised or not; when or how a function is, or is not, to be exercised; conditions that must be met before a function is exercised (for example, conditions 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.

527 The power of direction supplements other mechanisms for the Secretary of State to impose obligations on NHS England, such as the Mandate, which remains the primary mechanism through which the Secretary of State will set out the priorities that NHS England should be seeking to achieve.

528 As clarified in subsections 13ZC(7) and (8) the power to direct in new section 13ZC(1) is not generally limited by the Secretary of State's other statutory functions but is limited by other powers to make regulations and orders. The directions therefore 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.

529 Section 13ZD sets out the exceptions to the power in section 13ZC(1). The Secretary of State cannot use the power in 13ZC(1) to give directions to NHS England in relation to the appointment or employment of individuals by NHS England; in relation to individual clinical decisions; or in relation to drugs or treatments that the National Institute for Health and Care Excellence (NICE) has not recommended or issued guidance on as to its clinical and cost effectiveness.

530 The section also repeals 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. The new section 13ZE(1) allows for a specific type of direction to be given under section 13ZC which states that the Secretary of State considers NHS England to be failing or have failed to discharge any of its functions , and that the direction is aimed at addressing that failure. If NHS England fails to comply with this type of direction, the Secretary of State may intervene to discharge the relevant functions or arrange for their discharge by another person. Where the Secretary of State chooses to intervene in this way, they must publish their reasons for doing so. Sub-section (4) of the new section 13ZE clarifies that, for the purposes of the section, a failure to discharge a functions includes a failure to discharge it properly, and a failure to discharge it properly includes a failure to discharge it consistently with what the Secretary of State considers to be in the best interests of the health service.

531 The section also introduces section 13ZF which gives the Secretary of State powers to direct NHS England to provide information and repeals paragraph 14 of Schedule A1 to 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. A direction under this section may also require NHS England to use any powers they hold to obtain this information from others (such as integrated care boards) if required.

Section 46: Reconfiguration of services: intervention powers

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

Schedule 6: Intervention powers over the reconfiguration of NHS services

533 Schedule 6 inserts a new Schedule 10A into the NHS Act 2006. The Schedule sets out a new intervention power in relation to the reconfiguration of NHS services.

534 Paragraph 1 of Schedule 10A provides definitions of NHS commissioning body, NHS services, NHS trusts and the reconfiguration of NHS services for the purposes of the Schedule.

535 Paragraph 2 places a duty on an NHS commissioning body to notify the Secretary of State when there is a "notifiable" proposal to reconfigure services. "Notifiable" is to be specified in regulations.

536 Paragraph 3 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.

537 Paragraph 34 sub-paragraph (2) allows the Secretary of State to take on the decision-making role of the NHS commissioning body within 6 months of having made a direction calling in the proposal. The Secretary of State must notify the NHS commissioning body once they have finished considering the proposal.

538 Paragraph 3 sub-paragraph 3 gives some examples of the decisions Secretary of State may choose to take when giving a direction for the reconfiguration of NHS services, but is not intended to be exhaustive. 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.

539 Paragraph 3 sub-paragraph (4) requires the Secretary of State to give relevant bodies the opportunity to make representations in relation to the proposal before taking a decision on the proposal. This must include the NHS commissioning body; if the NHS commissioning body is an integrated care board, NHS England; each local authority to whose area the proposed reconfiguration relates; and any other person the Secretary of State considers appropriate.

540 Paragraph 3 sub-paragraph (5) provides that where the Secretary of State has made a decision under sub-paragraph (2)(a), that decision must be published together with an explanation of the reasons for taking it, and the NHS commissioning body must be notified of the decision and the reasons.

541 Paragraph 3 sub-paragraph (6) requires the Secretary of State to publish a summary of representations made under sub-paragraph (4)

542 Paragraph 4 subparagraphs (1)-(3) apply where the Secretary of State has called in a proposal under paragraph 34(1). While the Secretary of State is considering the proposal the NHS commissioning body must pause all work on the proposal, unless explicitly permitted in the direction. Once the Secretary of State has made a decision the NHS commissioning body must then give effect to that decision.

543 Paragraph 5 subparagraph (1) gives Secretary of State the power to direct an NHS commissioning body to consider a reconfiguration of NHS services. This allows the Secretary of State to act as a catalyst where the Secretary of State thinks a reconfiguration may be necessary.

544 Paragraph 5 sub-paragraph (2) requires the Secretary of State to publish any such direction made under paragraph 5(1), together with an explanation of the reasons for giving it.

545 Paragraph 6 provides a power for the Secretary of State's to require information or assistance from an NHS commissioning body, NHS trust or NHS foundation trust for the purposes of carrying out any functions under Schedule 10A.

546 Paragraph 7 sub-paragraph (1) places a duty on the Secretary of State to publish guidance for NHS commissioning bodies, NHS trusts and NHS foundation trusts about the exercise of their functions under this Schedule. The guidance could be used to outline the process of notification, call in process, and communication of decisions. The guidance must outline how the Secretary of State will exercise the functions under this Schedule.

547 Paragraph 7 sub-paragraph (2) place a requirement on NHS commissioning bodies, NHS Trusts and NHS Foundation Trusts to have regard to the guidance.

Section 47: Review into NHS supply chains

548 Subsection 1 requires the Secretary of State to carry out a review into the risk of slavery and human trafficking taking place in relation to people involved in NHS supply chains.

549 Subsection 2 allows the Secretary of State to determine which NHS supply chains to consider as part of the review or otherwise limit the scope of the review.

550 Subsection 3 specifies that the review must however include a significant proportion of the NHS supply chains for cotton based products in relation to which companies formed under section 223 of the NHS Act 2006 (taken as a whole) exercise functions.

551 Subsection 4 requires the Secretary of State to publish and lay before Parliament a report on the outcome of the review within 18 months of the section coming into force.

552 Subsection 5 specifies that this report must describe the scope of and methodology used in carrying out the review.

553 Subsection 6 requires that the report must include any views of the Secretary of State as to steps that should be taken to mitigate the risk of slavery and human trafficking taking place in relation to people involved in NHS supply chains.

554 Subsection 7 requires NHS England to assist in the carrying out of the review or the preparation of the report, if requested to do so by the Secretary of State.

555 Subsection 8 defines the health service in England, the NHS supply chain, and slavery and human trafficking for the purposes of this section.

NHS Trusts

Section 48: NHS trusts in England

556 This section repeals section 179 of the 2012 Act. Section 179 of the 2012 Act was never commenced. If commenced, it would have abolished NHS Trusts in England. However not all NHS Trusts have converted to NHS Foundation Trusts. NHS Trusts still exist and will continue to exist and so this section of the 2012 Act has been repealed to avoid any confusion regarding the future existence of NHS trusts.

Section 49: Removal of power to appoint trust funds and trustees

557 This section repeals paragraph 10 of Schedule 4 to the NHS Act 2006. This paragraph allowed the Secretary of State to appoint trustees for an NHS Trust to hold property on Trust. This section therefore removes the Secretary of States powers to appoint such Trustees.

Section 50: Sections 48 and 49: consequential amendments

558 This section 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

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

Section 51: Licensing of NHS Trusts

560 This section removes the exemption on NHS trusts to hold a license from NHS England (previously Monitor).

561 Subsection (2) inserts a new section 87A into the 2012 Act, which requires 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.

562 Subsection (2) also requires NHS England to treat existing NHS Trusts as if they had been established on the day of commencement of section 51(1) of the Act for the purposes of licenses under section 85 and the application of section 87A(1).

Section 52: NHS Trusts: wider effect of decisions

563 This provision, which is inserted into the NHS Act 2006 as the new section 26A, sets out a new duty on English NHS Trusts, which also applies to the other "relevant bodies". The "relevant bodies" are integrated care boards (new section 14Z43), NHS England (new section 13NA) and NHS Foundation Trusts (new section 63A).

564 This duty has been described operationally as the "triple aim" duty.

565 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.

566 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 (paragraph (a)), the quality of services provided or arranged by relevant bodies (paragraph (b)) and the efficiency and sustainability of resources used by the relevant bodies (paragraph (c)).

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

568 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. Under subsections (b) and (c), it also specifies that when complying with the Triple Aim duty, the relevant bodies must consider inequalities in health and well-being and the benefits obtained from services when considering the effects of their decisions on the areas in subsections (1)(a) and (b).

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

Section 53: NHS Trusts: duties in relation to climate change

570 *Duties as to climate change:* The Act introduces a new duty on NHS Trusts that requires each Trust to have regard to how it contribute to the achievement of the government's legislative targets regarding the environment and climate change. These are specified as: the target set under section 1 of the Climate Change Act 2008 (the Net Zero emissions targets, currently set for 2050) and the targets due to be set under section 5 of the Environment Act 2021, which will pertain to such matters as air quality, water quality and species abundance (among others). In addition, the duty requires each Trust to have further regard to how it may support efforts to adapt to the predicted impacts of climate change as set out in reports brought forward under section 56 of the Climate Change Act 2008. The duty applies when a Trust is exercising any of its functions. Subsection (2) requires Trusts to have regard to any guidance issued by NHS England on how it is to discharge this duty.

Section 54: Oversight and support of NHS trusts

571 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).

Section 55: Directions to NHS trusts

572 This section inserts a new section 27B into the NHS Act 2006 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.

573 Under subsection (2), this section 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 or paragraph 25(3) of Schedule 4 of the NHS Act 2006, NHS England's direction under this section would have no effect.

574 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.

575 Subsection (3) of the section 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.

576 Subsection (4)(a) amends paragraph 20(2) of Schedule 4 to the NHS Act 2006, which limits the circumstances in which NHS trusts can generate additional income. The amendment expands the list of limitations to allow NHS England to specify in directions given under the new power in section 27B circumstances in which NHS trusts much seek NHS England's consent to exercise certain functions in order to generate additional income.

577 Subsection (4)(b) amends paragraph 25 of Schedule 4 to the NHS Act 2006, to ensure that any directions given by NHS England under the new section 27B of that Act are added to the things NHS trusts must have regard to in respect of staff employment including staff pay, allowances, terms and conditions.

Section 56: Recommendations about restructuring of NHS trusts

578 This section 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.

Section 57: Intervention in NHS Trusts

579 This section 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 English NHS trust under section 66(2) of the NHS Act 2006 or a default order in relation to an NHS trust under section 68(2) of the NHS Act 2006. NHS England will also be required, under section 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.

580 Previously the TDA was directed by the Secretary of State under the 2016 Directions, to make such recommendations.

Section 58: NHS Trusts: conversion to NHS foundation trusts and dissolution

581 Subsection (2) amends section 33 of the NHS Act 2006 so that an application by an NHS Trust to become a Foundation Trust, no longer requires the support of the Secretary of State. Subsection (3) amends section 35 of the NHS Act 2006 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.

582 Subsection (5) also amends paragraphs 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.

Section 59: Appointment of chair of NHS trusts

583 This section amends paragraph 3(1)(a) of Schedule 4 (Appointment of chair of directors of NHS Trust) to the NHS Act 2006 provides for NHS England to appoint the chair of the board of directors for an NHS trust. This replaces the Secretary of State appointing the chair.

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

Section 60: Financial Objectives for NHS trusts

585 This section substitutes new paragraphs into Schedule 5 to the NHS Act 2006.

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

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

588 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

Section 61: Licensing of NHS Foundation Trusts

589 This section amends section 88 of the 2012 Act. Section 88 requires that NHS England 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.

590 The new subsection (1) requires NHS England to 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 of the 2012 Act.

Section 62: Capital Spending Limits for NHS Foundation Trusts

591 This section amends the NHS Act 2006, to give NHS England the power to set a capital expenditure limit on an NHS Foundation Trust.

592 Subsection (2) inserts sections 42B and 42C into the NHS Act 2006.

593 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 single financial year. The order must state the financial year and the trust which it applies to, as well as the expenditure limit.

2. Subsections (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 it is in the public domain.

3. Subsection (5) allows NHS England to set a limit either during, or before the financial year to which the limit relates.

4. Subsection (6) imposes a statutory duty on the NHS Foundation Trust not to exceed the capital expenditure limit as specified in the order.

5. Subsection (7) defines 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.

594 Section 42C(1) requires NHS England to produce guidance on the use of its power to make orders under section 42B, and subsection (2) requires NHS England to consult with the Secretary of State before publication of such guidance (or revised 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.

595 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.

596 Section 42C(4) provides that order made by NHS England under section 42B will not be a statutory instrument.

Section 63: Accounts, annual reports, and forward plans

597 This section amends section 43 of and paragraph 27 of Schedule 7 to the NHS Act 2006 and sections 155 and 156 of the 2012 Act.

598 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. Section 155 was never brought into force; it looked 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 paragraph (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 though section 54(1) of this Act.

Section 64: NHS foundation trusts: joint exercise of functions

599 This section 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.

Section 65: NHS foundation trusts: mergers, acquisitions and separations

600 This section amends sections 56 (mergers), 56A (Acquisitions) and 56B (Separations), of the NHS Act 2006.

601 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.

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

603 Subsection (3)(a) amends section 56A(3) to remove the 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.

604 Subsection (3)(b) amends subsection 56A(4), placing 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 or otherwise must refuse the application.

605 Subsection (4) amends section 56B(4) (separations) placing 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 or otherwise must refuse the application.

Section 66: Transfers on dissolution on NHS foundation trusts

606 This section amends subsections 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.

607 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.

608 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.

Section 67: NHS foundation trusts: wider effect of decisions

609 This provision, which is inserted into the NHS Act 2006 as the new section 63A, sets out a new duty on NHS foundation trusts, which also applies to the other "relevant bodies". The "relevant bodies" are integrated care boards (new section 14Z43), NHS England (new section 13NA) and NHS Trusts in England (new section 26A).

610 This duty has been described operationally as the "triple aim" duty.

611 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 (paragraph (a)), the quality of services provided or arranged by relevant bodies (paragraph (b)) and the efficiency and sustainability of resources used by the relevant bodies (paragraph (c)).

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

613 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. Under subsections (b) and (c), it also specifies that when complying with the Triple Aim duty, the foundation trust must consider inequalities in health and well-being and the benefits obtained from services when considering the effects of their decisions on the areas in subsection(1)(a) and (b).

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

Section 68: NHS Foundation Trusts: duties in relation to climate change

615 *Duties as to climate change:* The Act introduces a new duty on NHS Foundation Trust that will require each Foundation Trust to have regard to how it can contribute to the achievement of the government's legislative targets regarding the environment and climate change. These are specified as: the target set under Section 1 of the Climate Change Act 2008 (the Net Zero emissions targets, currently set for 2050) and the targets due to be set under Section 5 of the Environment Act 2021, which will pertain to such matters as air quality, water quality and species abundance (among others). In addition, the duty requires each Foundation Trust to have further regard to how it may support efforts to adapt to the predicted impacts of climate change as set out in reports brought forward under section 56 of the Climate Change Act 2008. The duty applies to Foundation Trusts when exercising any of their functions. Subsection (2) requires Foundation Trusts to have regard to any guidance issued by NHS England on how it is to discharge this duty.

NHS Trusts and NHS Foundation Trusts: transfer schemes

Section 69: Transfer schemes between trusts

616 This section inserts section 69A into the NHS Act 2006.

617 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 NHS body is defined in subsection (8).

618 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.

619 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).

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

621 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).

622 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.

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

624 Subsection (7)(b) notes a transfer of property includes a grant of a lease.

625 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.

Section 70: Trust special administrators

626 This section introduces Schedule 8 to the Act which amends Chapter 5A of the NHS Act 2006 (Trust Special Administrators: NHS trusts and NHS foundation trusts).

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

627 This Schedule outlines the changes to the process and authorisation for the appointment of trust special administrators, including the reporting mechanisms, amending sections of Part 2, Chapter 5A (Trust Special Administrators: NHS Trusts and NHS foundation trusts) of the NHS Act 2006 as follows.

628 Paragraph 2 of the Schedule substitutes a new section 65B to reflect the formal merger under this Act of the TDA and Monitor into NHS England.

629 Subsection 65B(1) transfers the responsibility for appointing a trust special administrator to an NHS trust from the Secretary of State to NHS England. Subsection 65B(2)(a) introduces a requirement for NHS England to appoint a trust special administrator if required to do so by the Care Quality Commission (CQC), as is already required for NHS foundation trusts. Otherwise, under section 65B(2)(b), NHS England 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 making of the order.

630 Subsection 65B(3) enables the CQC to 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. Subsection 65B(4) adds any integrated care board in whose area the trust has hospitals, establishments or facilities to the list of bodies that the CQC must consult.

631 Similarly, 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 paragraph 65B(2)(b), section 65B(5) adds any integrated care board in whose area the trust has hospitals, establishments or facilities to the list of bodies that NHS England must consult before making the order.

632 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 (which must be within 5 working days of the order being made) and must lay before Parliament a report stating the reasons for making an order.

633 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.

634 Section 65BA places a duty on the 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, as is currently required in relation to NHS foundation trusts.

635 Paragraphs 3 and 4 replace the name of the regulator, formerly Monitor, with NHS England. NHS England is now responsible for appointing a trust special administrator for foundation trusts, The requirement to indemnify a trust special administrator has been removed from section 65D(12) and replaced with a provision allowing NHS England to pay remuneration and expenses, which replicates the provision in relation to NHS trusts.

636 Paragraph 5 of the schedule amends section 65F, replacing the requirement for 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 draft report is to contain recommended action which, in the case of an 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 (sections 65F(1) and 65F(1A)).

637 Section 65F(1B) sets out the circumstances in which a trust special administrator may not provide a draft report under subsection (1A).

638 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 directs the administrator should consult, and the CQC (section 65F(2)).

639 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.

640 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)).

641 Paragraph 6 of this schedule makes amendments to Section 65G, replacing the references to the regulator to NHS England and including amended or new provisions for NHS England and CQC.

642 Section 65G(5) is replaced by the insertion of a new subsection which replaces the name of “The Board” with “NHS England” with the substance of that provision remaining unchanged.

643 A new subsection (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); 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.

644 Paragraph 7 of this schedule makes amendments to section 65H.

645 Sections 65H(7) and (8), which deal with persons from whom the trust special administrator must seek written responses to the draft report, are now amalgamated into section 65H(7) 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)).

646 Sections 65H(10) and (10A) have been replaced by a new section 65H(10) so that the Secretary of State may now direct NHS England as to the persons from whom it should direct the administrator to request a written response and seek a response through holding a meeting.

647 As NHS England will be responsible for appointing a trust special administrator for both NHS trusts and foundation trusts, section 65H(13) has been repealed as this is dealt with in new section 65H(10).

648 Paragraph 8 of this schedule makes amendments to section 65I, to include a requirement for the trust special administrator to report to NHS England as well as the Secretary of State with respect NHS trusts.

649 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 trust. The period for receipt of the report remains unchanged (section 65I(1) and (1A)).

650 Subsection (3) is amended to place a duty on NHS England rather than Secretary of State to lay the final report in parliament.

651 Paragraph 9 of this schedule makes amendments to section 65J, 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)).

652 Section 65J(5) is repealed as NHS England regulates both NHS trusts and foundation trusts.

653 Paragraphs 10 and 11 of this schedule substitute a new section 65K. In relation to NHS trusts, both NHS England and the Secretary of State are to receive the administrator's 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 taken, the 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. This reflects the responsibility that NHS England now has for the appointment of trust special administrators.

654 Paragraphs 12 to 14 of this schedule replace references to the "regulator" with "NHS England".

655 Paragraph 15 of this schedule amends section 65KD. 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 boards in section 14Z61 of the NHS Act 2006 while prohibiting NHS England from exercising that power (section 65KD(5)).

656 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 have been repealed as the Secretary of State's new power of direction over NHS England in section 45 can achieve the same effect.

657 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 over NHS England can achieve the same effect.

658 Paragraph 16 of this schedule makes amendments to section 65L.

659 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 comes to an end (section 65L(1) and (2)).

660 In relation to a 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 NHS England must 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).

661 Paragraph 17 of this schedule amends section 65LA, replacing in the reference to "the regulator" with "NHS England".

662 Paragraph 18 of this schedule amends section 65M, to provide that NHS England, not the Secretary of State, is responsible for appointing a replacement administrator.

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

664 Paragraph 19 amends section 65N, 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.

665 Paragraph 20 makes consequential amendments to section 65O.

666 Paragraph 21 amends section 272 (orders, regulations, rules and directions) so that an order made under section 65L(2B) is not subject to a parliamentary procedure, which aligns with orders made under section 65L(2).

Joint Working and Delegation of Functions

Section 71: Joint working and delegation arrangements

667 This section inserts new provisions into the NHS Act 2006.

668 *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 set out other bodies to be added to the definition of a relevant body and be party to the arrangements under subsection (1). It will also be possible to set out in regulations under subsection (3) which functions are not subject to arrangements made under subsection (1), or the extent to which they could be included in arrangements or where certain conditions should apply to the exercise of the power at subsection (1). Under subsection (4), powers under this section 65Z5 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. 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.

669 *Section 65Z6 Joint committees and pooled funds.* This section 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.

670 *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) or prescribed under subsection (2)(e) must have regard to that guidance.

671 Under subsection (3) of section 71 of this Act, section 75(7B) 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, it can be treated as an NHS body under section 75 of the NHS Act 2006.

Section 72: References to functions: treatment delegation arrangements etc.

672 This section 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.

673 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.

674 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, previous sections 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.

675 There may be some provisions within the NHS Act 2006 where the starting point explained above would not produce the desired policy result. For example, it could be that a particular 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 this 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).

676 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.

677 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 2012.

Schedule 9: References to functions: treatment of delegation arrangements etc

678 This Schedule makes amendments to various enactments as a result of the insertion into the NHS Act 2006 of new section 7B, new section 65Z5 and new section 275A.

679 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 power for the Secretary of State to make arrangements under section 7A for NHS England, a integrated care board, a combined authority 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").

680 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.

681 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.

682 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.

683 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

Section 73: Repeal of duties to promote autonomy

684 This section amends the NHS Act 2006 by removing the Secretary of State and NHS England's duties to promote autonomy.

685 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. NHS England will continue to function as an arm's length body, but the removal of these duties also allows for the introduction of section 45 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 are in the interests of the public.

Section 74: Guidance about joint appointments

686 This section 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 and relevant NHS providers; relevant NHS bodies and local authorities; and relevant NHS bodies and Combined Authorities. In this section references to relevant NHS bodies are to NHS England, integrated care boards, English NHS trusts and NHS foundation trusts. This guidance could provide a clear set of criteria for organisations to consider when making joint appointments. Under subsection (3), relevant 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 persons.

Section 75: Co-operation by NHS bodies etc

687 This section amends sections 72 and 82 of the NHS Act 2006 and section 96 of the 2012 Act.

688 Section 72 of the NHS Act 2006 imposes a duty on NHS bodies, including some Welsh NHS bodies, to co-operate with each other. Section 75(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.

689 Section 82 of the NHS Act 2006 imposes a duty 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. S 75(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.

690 Section 96 of the 2012 Act specifies the purposes for which NHS England (previously Monitor) can set or modify licensing conditions of NHS health service providers. Previously 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.

691 Section 75(4)(a) of the Act amends section 96(2)(g) and section 96(3) of the 2012 Act 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) in connection with subsections 2(e) and (f) but means that modification of the licence under section 96(2)(g) is no longer conditional on achieving those objectives.

692 Subsection (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 in England.

Section 76: Wider Effect of decisions: licensing of health care providers

693 Section 96(2) of the 2012 Act specifies the purposes for which NHS England (previously Monitor) 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, integrated care boards, NHS Foundation Trusts and NHS Trusts, a new purpose for which licence conditions may be set or modified is created.

694 This section inserts new paragraph (da) into section 96(2). Paragraph (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 wider effect of decisions" new sections 14Z43, 13NA, 26A and 63A being inserted into the NHS Act 2006.

695 The new subsection (2A) provides the list of matters referred to at the new paragraph (da), which are the same as the matters in the new sections 14Z43, 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

Section 77: The NHS payment scheme

696 This section 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

697 This Schedule amends the national tariff provisions in the 2012 Act to introduce the NHS payment scheme, the new system for determining the price to be paid by commissioners for health care services.

698 Paragraph 2 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.

699 Paragraph 3 replaces Chapter 4 of Part 3 of the 2012 Act with new sections 114A to 114F to make provision about the NHS payment scheme.

700 New section 114A(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 purposes of the NHS and for the services that are provided through arrangements made by NHS England or an integrated care board under the Secretary of State's public health functions under section 7A or 7B of the NHS Act 2006.

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

702 Subsection (3) sets out what rules may do and what they may specify. For example, this could include specifying prices or specifying a formula as a basis to determine prices; making different provision for services by reference to other factors; or the rules may confer a discretion on the commissioner of a service or on NHS England.

703 Subsections (4) and (5) state that rules under subsection (1) can allow or require prices to be agreed between commissioners and providers of a service, and, where they are so agreed, the rules may set out how they are to be agreed and whether they are to be published.

704 Subsection (6) retains in substance the provision formerly in section 119(1) of the 2012 Act 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, by ensuring that regard is had to cost differences and to differences in the range of services that providers provide.

705 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.

706 Subsection (8) allows the NHS payment scheme to contain guidance on the application of the rules and subsection (9) specifies that a commissioner is required to have regard to that guidance.

707 Subsection (10) in substance replicates what was formerly in section 116(12) to clarify that the NHS payment scheme has effect for the period specified in it or, where a new edition takes effect before the end of that period, until the new edition takes effect.

708 New section 114B provides NHS England with a power of direction over commissioners where they fail to comply with the rules in the NHS payment scheme.

709 Section 114C sets out the requirements on NHS England to carry out an impact assessment and consultation on the NHS payment scheme. It places a duty on NHS England to carry out an impact assessment or publish a statement if it concludes that assessment is not needed, before publishing the NHS payment scheme. Before publishing the NHS payment scheme NHS England must also consult each integrated care board, relevant providers and other persons who NHS England considers appropriate. Section 114C(3) to (8) sets out the consultation process and the definition of a relevant provider for these purposes. 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) of the 2012 Act.

710 Section 114D replaces what was formerly section 120 of the 2012 Act and deals with objections to the proposed NHS payment scheme during the consultation period. Where a prescribed percentage of integrated care boards or providers object to the proposed NHS payment scheme, NHS England is required to consult such persons as appear to be representative of the integrated care boards or relevant providers who objected (section 114D(1) to (3)). 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)).

711 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 its decision, and share it with integrated care boards and relevant providers who objected to the proposed scheme (section 114D(5)).

712 New section 114E(1) sets out how amendments of the NHS payment scheme are made and allows NHS England to revise the payment scheme during the period for which it operates, on the condition that NHS England must be satisfied that any revisions are not significant enough to require the publication of a new NHS payment scheme.

713 When deciding whether the amendments are significant enough to require publication of a new NHS payment scheme NHS England must have regard to: the proportion of integrated care boards and 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 prices resulting from the revisions (section 114E(2)).

714 Section 114E(3) places a duty on NHS England to publish the NHS payment scheme as amended.

715 Subsection (4) of section 114E requires NHS England to consult with integrated care boards, relevant providers and any other appropriate persons that would be affected by the proposed amendments to the NHS payment scheme before making the amendments.

716 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 integrated care boards, relevant providers and any other appropriate persons.

717 New section 114F sets out the definitions for "commissioner", "the NHS payment scheme" and "relevant provider" as referred to throughout Chapter 4.

718 Paragraph 4 of Schedule 10 amends section 304(5)(g) of the 2012 Act to refer to the NHS payment scheme rather than the national tariff, to ensure that regulations made under section 114D(1)(b) setting out the objection percentages are subject to the affirmative procedure.

Patient Choice and Provider Selection

Section 78: Regulations as to patient choice

719 This section amends the NHS Act 2006 to insert provisions relating to patient choice.

720 Subsection (2) amends the existing section 6E which allows regulations to place "standing rules" on commissioners. The existing power to issue regulations under this section is changed from a "may" to a "must". This and the obligation inserted as a new subsection 1A means that these regulations must contain provisions about how NHS England and integrated care boards will allow patients to make choices about their care. Subsection (2) also inserts provision stating that the regulations may make other 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) of section 6E in the NHS Act 2006 is removed as it has been replaced by these new provisions.

721 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 new section 6F(1) NHS England may investigate an integrated care board in relation to their compliance with the regulations made under section 6E and, under section 6F(2) NHS England may issue directions to integrated care boards to prevent, remedy, or mitigate the effects of failures. Section 6F(3) provides that, during or following an investigation, NHS England may accept an undertaking from the integrated care board that it will take actions regarding the actual or likely failure to comply. If NHS England accepts an undertaking, by virtue of section 6F(4), it may 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. Section 6F(5) requires NHS England to take partial compliance into account.

722 Subsection (3) also inserts the new section 6G. Section 6G(1) requires NHS England to publish guidance on how it intends to exercise its powers to investigate, direct on, and accept undertakings about patient choice under the new section 6F and Schedule 1ZA. Section 6G(2) requires NHS England to obtain the approval of Secretary of State before publishing guidance under section 6G(1).

723 Subsection (4) amends the existing provision in the NHS Act 2006 on NHS England's annual report to require the report to include an assessment of how effectively NHS England discharges its duties under the patient choice regulations made under those sections inserted by this provision and the existing duty to enable patient choice.

724 Subsection (5) gives effect to Schedule 11 of the Act, which inserts the new Schedule 1ZA (undertakings by integrated care boards) into the NHS Act 2006.

Schedule 11: Patient choice: undertakings by integrated care boards

725 This schedule contains further details about the procedure for undertakings under the new section 6F inserted into the NHS Act 2006 by section 78 of the Act.

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

727 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.

728 Paragraph 4 allows the undertaking to be varied by mutual agreement of the integrated care board giving the undertaking and NHS England.

729 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 has 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 beginning with the day after receiving the application.

730 Paragraph 6 outlines an appeal process. An integrated care board that has had an application for a compliance certificate refused can appeal 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 NHS England's decision or rule that it has no effect.

731 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.

Section 79: Procurement regulations

732 This section inserts a new section 12ZB into the NHS Act 2006, after section 12ZA.

733 Subsection (1) of the new section 12ZB enables the Secretary of State to make regulations in relation to the processes to be followed and objectives to be pursued by relevant authorities in 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.

734 Subsection (2) specifies that the regulations made under subsection (1) must include provision specifying steps to be taken when following a competitive tendering process.

735 Subsection (3) states that the regulations must, in relation to the procurement of all health care services to which they apply, make provision for the purposes of ensuring transparency, ensuring fairness, ensuring that compliance can be verified and managing conflicts of interest.

736 Subsection (4) requires that NHS England must publish such guidance as it considers appropriate about compliance with the regulations and subsection (5) places a requirement on the relevant authorities to have regard to the published guidance.

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

738 Subsection (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 all forms of health care provided for individuals, whether relating to physical or mental health.

Section 80: Procurement and patient choice: consequential amendments etc

739 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 regulation making power (section 12ZB). Subsection (1) also amends section 272 of the NHS Act 2006 to provide that regulations made under the new section 12ZB will be subject to the draft affirmative procedure.

740 Subsection (2) removes the existing regulation making powers on procurement, patient choice and competition from the 2012 Act.

741 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 National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

742 Subsection (4) revokes the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.

Section 81: Eradicating slavery and human trafficking in supply chains

743 Subsections (1) and (2) of section 81 insert a new section 12ZC into the NHS Act 2006. Subsection (1) of the new section 12ZC requires the Secretary of State to make regulations with such provision as the Secretary of State thinks appropriate with a view to eradicating the use in the health service in England of goods or services that are tainted by slavery and human trafficking.

744 Subsection (2) of the new section 12ZC sets out that the regulations may include provision for procurement processes, including provision as to the circumstances in which suppliers must or may be excluded from consideration for the award of a contract; steps that must be taken by public bodies to assess and address the risk of slavery and human trafficking in health service supply chains; and matters to be included in contracts for goods or services procured for the health service.

745 Subsection (3) of the new section 12ZC defines health service supply chains as supply chains for procuring goods or services for the health service in England; public bodies as bodies exercising functions of a public nature; slavery and human trafficking as defined in section 54(12) of the Modern Slavery Act 2015, which includes conduct which constitutes an offence under a number of slavery and human trafficking acts, including the first part of the Modern Slavery Act 2015, and similar conduct taking place outside of the United Kingdom; and defines goods or services as "tainted" by slavery and human trafficking if it takes place in relation to anyone involved in the supply chain for providing those goods or services.

746 Subsection (3) of section 81 amends section 272 of the NHS Act 2006 to ensure that any regulations made under this power are subject to the affirmative procedure.

Competition

Section 82: Duty to provide assistance to the CMA

747 Section 82(1) inserts a new section 13SC into the NHS Act 2006.

748 Section 13SC(1) places NHS England under a duty to share with the CMA 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. Section 13SC(2) defines regulatory information as information held by NHS England in relation to its functions under section 13SB(2)(a) or (b) of the NHS Act 2006 (which is being inserted by this Act, and lists NHS England's regulatory functions) or its functions under provisions being inserted into the NHS Act 2006 by this Act in relation to the enforcement of patient choice and the oversight, support and restructuring of NHS Trusts (the new sections 6F, 27A and 27C of and Schedule 1ZA to the NHS Act 2006).

749 Section 13SC(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 on behalf of the CMA by the CMA Board or a CMA group (within the meaning of Schedule 4 to the Enterprise and Regulatory Reform Act 2013).

750 Section 82(2) omits Section 80 of the 2012 Act, relating to previous co-operation arrangements between Monitor and the CMA.

Section 83: Mergers of providers: removal of CMA powers

751 This section amends the NHS Act 2006 to insert a new Section 72A after Section 72.

752 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.

753 Section 72A, subsection (2) clarifies that the merger of two or more relevant enterprises (e.g. NHS foundation trusts) with one or more enterprises that are not relevant NHS enterprises (e.g., a private healthcare provider) is still in scope of the merger control regime.

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

755 This section 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.

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

Section 84: Removal of functions relating to competition etc.

757 This section amends the 2012 Act to remove sections 72 and 73 of that Act. Sections 72 and 73 of the 2012 Act provided for Monitor's concurrent competition functions with the CMA.

758 This section also provides for Schedule 12, which contains consequential amendments.

Schedule 12: Removal of functions relating to competition etc

759 This Schedule contains amendments which are consequential on the removal of Monitor's

functions relating to competition. It amends the:

- Company Directors Disqualification Act 1986
- Competition Act 1998
- Enterprise Act 2002
- Health and Social Care Act 2012
- Enterprise and Regulatory Reform Act 2013
- Care Act 2014

Section 85: Removal of CMA's involvement in licensing etc.

760 This section amends the 2012 Act regarding NHS licensing. 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.

761 Subsection (2) removes the need for Monitor (which is being merged into NHS England as part of this Act), 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.

762 Subsection (3) repeals subsections (6) to (9) of section 100 of the 2012 Act. These subsections 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.

763 Subsection (4) repeals section 101 of the 2012 Act, which allows Monitor to refer contested licence conditions to the CMA.

764 Subsection (5) amends section 103, subsection 3 in the 2012 Act to refer to licensing 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.

765 Subsection (6) removes references to section 142 from section 141 of the 2012 Act. Section 142 is repealed by subsection (7).

766 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 that Act.

767 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

Section 86: Special Health Authorities: removal of 3 year limit

768 This section removes the legislative provisions that imposed a three-year time limit on any new Special Health Authority.

769 Subsection (1) repeals section 28 and section 272(6)(zc) of the NHS Act 2006, which were new sections inserted by the 2012 Act (section 48) in order to impose the three-year time limit.

770 Subsection (2) makes changes to the 2017 Order used to create the NHS Counter Fraud Authority, to reflect that there is no longer an abolition date.

771 Subsection (3) repeals section 48 of the 2012 Act, which inserted the provisions repealed by subsection (1) into the NHS Act 2006.

Section 87: Tidying up etc provisions about accounts of certain NHS bodies

772 This section sets out requirements for Special Health Authorities in relation to their accounts and auditing.

773 Subsection (1) inserts a new section 29A after section 29 of the NHS Act 2006.

774 Subsection (1) of the new section 29A clarifies that this section applies to Special Health Authorities that perform functions only or mainly in respect of England, or Special Health Authorities that neither perform functions only or mainly in respect of England, nor perform functions only or mainly in respect of Wales.

775 Subsection (2) of the new section 29A requires Special Health Authorities to keep proper accounts and records.

776 Subsection (3) of the new section 29A gives the Secretary of State the power to give a direction to a Special Health Authority about the form of its accounts.

777 Subsections (4), (5), (6) and (7) of the new section 29A 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.

778 Subsections (8) and (9) clarify that the requirements in subsection (2) do not require a Special Health Authority's annual accounts to include matters relating to a charitable trust of which it is the trustee, and that the directions made under subsection (4) do not have effect in relation to such a charitable trust's accounts.

779 Subsection (2) of section 87 inserts paragraph 11A into Schedule 4 to the NHS Act 2006.

780 Paragraph 11A sets out requirements on NHS Trusts in relation to accounts, record-keeping and audit.

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

782 Subparagraph (2) of new paragraph 11A gives the Secretary of State the power to give a direction to an NHS Trust about the form of its accounts.

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

784 Subparagraph (4) directs NHS Trusts to the Local Audit and Accountability Act 2014 for provision in relation to their audit.

785 Subparagraph (5) sets out the role of the Comptroller and Auditor General in examining the accounts and any report on them by the auditor or auditors.

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

787 Subparagraphs (7) and (8) clarify that subparagraph (1) does not have any effect in relation to accounts relating to a charitable trust of which the NHS Trust is a trustee, and that sub-paragraph (3) does not require the Trust's annual accounts to include matters relating to such a charitable trust.

788 Section 87(3) makes consequential amendments to the National Audit Act 1983, the NHS Act 2006, and the Local Electoral Administration and Registration Services (Scotland) Act 2006.

Section 88: Meaning of "health" in NHS Act 2006

789 This section amends section 275(1) of the NHS Act 2006 (interpretation) to clarify that "health" includes mental health. Previously provisions of the NHS Act 2006 were inconsistent about whether they mentioned mental health expressly. This amendment mitgates the risk of confusion by making the inclusion of mental health express.

Section 89: Repeal of spent powers to make transfer schemes

790 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.

791 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 were transferred under a scheme under section 300(1) of the 2012 Act (before its repeal) from a Primary Care Trust, a Strategic Health Authority or the Secretary of State to a Special Health Authority or a qualifying company. Such property, rights or liabilities may be transferred under a further scheme to any of the bodies listed in section 302(2). Subsections (3) to (8) of the new section 302 make further provision in relation to those schemes.

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

Section 90: Abolition of Local Education and Training Boards

793 This section abolishes Local Education and Training Boards (LETBs). In consequence of this, it repeals sections 103 to 107 of and Schedule 6 to and amends sections 100, 108, 119 of, and Schedule 5 to, the Care Act 2014.

794 Subsection (4) repeals sections 103 to 107 of the Care Act 2014, which set out the local functions of HEE carried out by LETBs.

795 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.

Section 91: Hospital Patients with care and support needs: repeals etc

796 Section 91(1)(a) substitutes a new section 74 into the Care Act 2014 to revoke 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, and to grant local areas the flexibility to implement a hospital discharge model best suited to local needs and circumstances.

797 Subsection (1) of the new section 74 applies where the relevant trust is responsible for an adult hospital patient and considers that the patient is likely to require care and support following discharge from hospital. It places a duty on NHS trusts and foundation trusts to take any steps that they consider appropriate to involve the patient and any carer of the patient as soon as is feasible after it begins making any plans in relation to the patient's discharge. The aim of

this section is that, where appropriate, patients and carers are involved in decision-making about the patient's onward care from the earliest stages of discharge planning.

798 Subsection (2) of the new section 74 requires relevant trusts to have regard to any guidance issued by NHS England in performing their duty under subsection (1).

799 Subsection (3) of the new section 74 provides that, for the purposes of that section, a relevant trust is responsible for a hospital patient if the relevant trust manages the hospital.

800 Subsection (4) of the new section 74 provides that, for the purposes of that section, an "adult" is a person aged 18 or over; a "carer" is an individual who provides or intends to provide care for an adult, otherwise than by virtue of a contract or as voluntary work; and a "relevant trust" is an NHS trust or an NHS foundation trust. The definition of "carer" for the purposes of this section is broader than the definition elsewhere in the Care Act 2014 as it includes young carers. This will ensure that young carers are involved in discharge planning, where the relevant trust considers it is appropriate to do so.

801 This section replaces section 74 of the Care Act 2014, which gave effect to Schedule 3 to the Care Act 2014. Subsection (1)(b) of the section repeals Schedule 3 to the Care Act 2014 in its entirety.

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

803 Further, in repealing Schedule 3 to the Care Act 2014 in its entirety, subsection (1)(b) repeals the provisions which enabled the responsible NHS body to charge the relevant local authority via a penalty notice, where a patient's discharge from hospital had 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.

804 Subsection (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 no longer have any application. The Community Care (Delayed Discharges etc) Act 2003 is therefore repealed in its entirety, as it is no longer required in England or in Wales.

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

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

Part 2: Health and Adult Social Care Information

Section 92: Information about payments etc to persons in the health care sector

807 Subsection (1) enables the Secretary of State to make regulations requiring manufacturers and commercial suppliers of health care products, and connected persons, to either publish (subsection (1)(a)) or provide to the Secretary of State (subsection (1)(b)) information about payments or other benefits provided by them to relevant persons. The terms *commercial supplier* and *manufacturer* are defined in subsection (12). The terms *connected person* and *relevant person* are described in Subsection (11) and will be defined further in regulations made under this section.

808 Subsection (2) enables the regulations made under subsection (1) to make provision about *when* and *how* the information must be published or provided. For example, this could include specific requirements about the frequency that information must be either published or provided and the place where the information must be published.

809 Subsection (3) describes the type of provision the regulations may make about the information which must be published or provided pursuant to subsection (1). For example, this may include the name of the recipient or provider of the payment/benefit, the value of the payment/benefit, and the reason for which the payment was made or the benefit given. This is a non-exhaustive list.

810 Subsection (4) enables regulations to make provision permitting or requiring the further sharing, publication or use of the information. For example, this would enable regulations to make provision about the Secretary of State's ability to share information received with others and provision about how those persons can use that information where this will assist with the publication of the information.

811 Subsection (5) enables regulations to make provision requiring manufacturers, commercial suppliers, and connected persons to retain information relating to payments or other benefits provided by them to relevant persons. This ensures that there is a record maintained which can be used to support enforcement activity.

812 Subsection (6)(a) enables regulations made under subsection (1) to authorise the Secretary of State to designate a reporting scheme operated by someone other than the Secretary of State as a "relevant scheme" if the Secretary of State considers that the provision of information under the alternative scheme would render compliance with some, or all, of the requirements imposed by regulations made under subsection (1) unnecessary. Subsection (6)(b) enables regulations made under subsection (1) to create exceptions from requirements to publish or provide information where manufacturers, commercial suppliers or connected persons provide information under a designated relevant scheme. The intention is that if a third party, (e.g. a trade association) operated a reporting scheme of an appropriate standard, persons participating in that scheme could be exempt from a requirement in the regulations made pursuant to subsection (1) to publish or provide information. Subsection (6)(c) enables provision to be made in the regulations requiring operators of relevant schemes to provide information they receive through the operation of relevant schemes to the Secretary of State and for the Secretary of State to publish this information. This would enable the Secretary of State to operate a comprehensive database of information about payments if necessary.

813 Subsection (7) enables the Secretary of State to place information retention requirements on persons running a relevant scheme as designated under subsection (6).

814 Subsection (8) clarifies that the provision for exceptions that may be made by the regulations includes authorising the Secretary of State to make discretionary exemptions from a requirement to publish or provide information in particular cases, on grounds specified in the regulations.

815 Subsection (9) enables the regulations to provide that the disclosure of information pursuant to the regulations will not breach an obligation of confidence or other restriction placed on the disclosure of the information. This is necessary to ensure policy aims around transparency are met and businesses are not prevented from publishing or providing information and the Secretary of State is not prohibited from making it publicly available. Subsection (9)(b) does not allow the creation of an exception from restrictions imposed by data protection legislation which will still need to be complied with.

816 Subsection (10) enables the regulations to limit the businesses subject to a requirement to report or provide information by reference to the manufacturers' or commercial suppliers' connection to the United Kingdom, or a part of it.

817 Subsection (11) defines connected person and relevant person. Subsection (11)(a) and (11)(b)(ii) allow these terms to be further defined in regulations.

818 Subsection (12) provides definitions for terms used in this section.

Section 93: Regulations under section 92 (information about payments etc to persons in the health care sector): enforcement

819 Subsection (1) enables regulations to make provision for the enforcement of the requirements set out in regulations made under section 92(1) including giving the Secretary of State the power to impose a financial penalty where a person, without reasonable excuse, fails to comply with a requirement imposed by regulations made under section 92 (Subsection (1)(a)) or provides false, misleading information (Subsection (1)(b)).

820 Subsection (2) requires the regulations to make provision about the amount of any financial penalty.

821 Subsection (3) provides that the regulations must include provision about the process for issuing a financial penalty including provision for an appeals process.

822 Subsection (4) enables regulations to make provision: enabling a notice of intent or final notice to be withdrawn or amended (paragraph (a)); enabling a final notice to be withdrawn in specified circumstances (paragraph (b)); enabling the financial penalty to be increased by a specified amount in the event of late payment (paragraph (c)); and detailing how a financial penalty would be recoverable (paragraph (d)).

Section 94: Regulations under section 92 (information about payments etc to persons in the health care sector): consent

823 Subsection (1) places an obligation on the Secretary of State to obtain the consent of the Scottish Ministers, Welsh Ministers, and Department of Health in Northern Ireland in relation to any provision in regulations made pursuant to section 92 which is within the legislative competence of the relevant devolved legislature, and is not merely incidental to, or consequential on, provision which would be outside the competence of that legislature. The subsection states that consent must be obtained before regulations are made.

824 Subsection (2) clarifies that the Secretary of State will not need to seek consent from the Northern Ireland Assembly where the provision would only incidentally affect a transferred matter and, if the provision were included in an Act of the Northern Ireland Assembly, the Act would require the consent of the Secretary of State under section 8 of the Northern Ireland Act 1998.

Section 95: Information standards

825 Subsection (2) amends section 250 (powers to publish information standards) of the 2012 Act, by substituting subsections (2) and (6), inserting new subsections (2A), (2B), and (6A) to (6D), and omitting subsection (5).

826 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).

827 New subsection (2A) provides that an information standard must specify to whom it applies.

828 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 care 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.

829 Subsection (5) of section 250 of the 2012 Act, which specified that an information standard must include guidance about implementation of the standard, is omitted.

830 The substituted subsection (6) requires the Secretary of State to have regard to any information standard published by NHS England which applies to the Secretary of State and to comply with any information standard published by the Secretary of State which applies to the Secretary of State.

831 New subsection (6A) provides that any other person to whom an information standard applies must comply with the standard, except in so far as the requirement to comply is waived as permitted in regulations made under subsection (6B).

832 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).

833 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.

834 New subsection (6D) signposts to section 277E of the 2012 Act for enforcement of information standards against persons other than public bodies.

835 Subsection (3) substitutes section 251 of the 2012 Act and inserts a new section 251ZA into that Act. The substituted section 251 requires regulations to set out the procedure to be followed in connection with preparing and publishing information standards under section 250 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.

836 The new section 251ZA (information standards: compliance) enables the Secretary of State to require documents, records or other 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) of the new section 251ZA signposts to section 277E of the 2012 Act in respect of enforcement against persons other than public bodies.

837 Subsection (4) inserts the definitions of "Health services", "Adult social care" and "public body" into section 251C of the 2012 Act.

838 Subsection (5) ensures that any regulations containing provisions made under section 250(6B) (waivers of information standards) or 251(1) (the procedure for setting information standards), will be subject to the draft affirmative procedure.

Section 96: Sharing anonymous health and social care information

839 This section 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.

840 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. 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).

841 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.

842 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).

843 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.

844 Subsection (5) signposts to section 277E of the 2012 Act in respect of enforcement against private health or social care providers.

845 Subsection (6) sets out the definitions of certain terms for the purposes of the new section 251D.

Section 97: General duties of the Health and Social Care Information Centre etc

846 This section 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 provision of health services and of adult social care in England when exercising its functions. Section 253(1) is also amended to clarify that the Information Centre has to have regard to the need to balance the needs mentioned in section 253(1) so far as they compete.

847 This section also amends section 261 (dissemination of information) of the 2012 Act so that the Information Centre 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 will put beyond doubt the Information Centre'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 approaches to the delivery of health and adult social care.

Section 98: Collection of information from private health care providers

848 This section 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.

849 Paragraphs (c) to (g) of this section make consequential amendments to section 259.

850 Paragraph (h) of this section signposts to new section 277E of the 2012 Act for the enforcement of requirements against persons other than public bodies and defines "health care providers".

Section 99: Collection of information about adult social care

851 This section 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.

852 New 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 in England or, where those services are commissioned by a Local Authority in England, outside England.

853 Subsection (2) stipulates that the Secretary of State can only require information if it is for purposes connected with the health care system, or the adult social care system, in England.

854 Subsection (3) enables the Secretary of State to specify the form and manner in which information must be provided, and when the information must be provided.

855 Subsection (4) states that the requirement to provide information must be in writing.

856 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 imposed by any enactment. This would include restrictions under the Data Protection Act 2018 and the UK GDPR.

857 Subsection (6) signposts to section 277E in respect of enforcement.

858 Subsection (7) defines "adult social care", "English local authority", and "relevant provider of adult social care services" for the purposes of section 277A.

859 Section 277B imposes restrictions on the disclosure of information provided under section 277A.

860 Subsection (1) restricts the disclosure of information provided under section 277A so that it may only be disclosed for purposes connected with the health care system or adult social care system in England.

861 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.

862 Subsection (3) sets out that subsections (1) and (2) do not restrict the disclosure of information where: consent has been given or the information has previously been lawfully disclosed to the public; or where the disclosure is in accordance with any court order, is necessary or expedient for the purposes of protecting the welfare of any individual, is necessary or expedient for the purposes of a person's 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.

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

864 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.

865 Subsection (2) empowers the Secretary of State to direct a Special Health Authority performing functions only or mainly 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.

866 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.

867 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.

868 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.

869 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.

Section 100: Enforcement of duties against private providers

870 This section inserts into Part 9 of the 2012 Act a new Chapter 4 containing section 277E which concerns provision in relation to enforcement and section 277F which concerns directions to a Special Health Authority to exercise the enforcement functions under regulations made under section 277E.

871 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 who, without reasonable excuse: fails to comply with an information standard unless the relevant requirement has been waived (subsection (1)(a)); fails to comply with a requirement to provide information imposed under section 251ZA(1), 251D(1)(b), 259(1)(a) or (aa), or 277A(1); or provides false or misleading information (subsection (1)(c)).

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

873 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.

874 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.

875 Subsection (5) sets out the definition of "public body".

876 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.

Section 101: Medicine Information Systems

877 Subsection (1) provides that the following provisions amend the Medicines and Medical Devices Act 2021.

878 Subsection (2) substitutes "Regulations: general" for the heading of Chapter 1 of Part 2.

879 Subsection (3) inserts a new Chapter 1A (Regulations: Information Systems) after Chapter 1 of Part 2 of the Medicines and Medical Devices Act 2021, which consists of a section 7A and 7B. The new section 7A confers a 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 (Power to make regulations about human medicines) of the Medicines and Medical Devices Act 2021. The definition reflects the position whereby key functions under the Human Medicines Regulations 2012 (S.I. 2012/1916) are carried out by the Licensing Authority, which consists of both Secretary of State and Northern Ireland Minister.

880 New 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 of human medicines, including the safety of clinical decisions relating to human medicines, and the quality and efficacy of 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.

881 Subsection (1)(a) and (c) of section 19 of the Medicines and Medical Devices Act 2021 makes specific provision 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.

882 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 ensure that the Information Centre is able to mandate the provision of specific information to be included in the information system and that the Information Centre is able to use and disclose such information.

883 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 considers necessary or expedient 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 may 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.

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

885 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.

886 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 information in a way that can be easily analysed by requiring providers to send information by a specific time and in a specific format.

887 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.

888 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.

889 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.

890 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.

891 Section 7A(6) provides a non-exhaustive list of 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, for example, the MHRA for the purpose of establishing registries.

892 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. This section also provides that where regulations confer a power on the appropriate authority to give a direction under section 7A(3)(d), the appropriate authority must consult with Scottish or Welsh Ministers before giving a direction that relates to Scotland or Wales respectively.

893 Section 7A(8) and (10) provides that where the Information Centre will require information from healthcare providers in Scotland and/or Wales, the regulations must allow for Scottish and or Welsh Ministers (as applicable), or a person designated by them, to collect the required data. Regulations will also be able to set out exceptions to this whereby, under certain circumstances, the Information Centre can collect the data directly. For these purposes, section 7A(9) and (11) enables regulations to confer powers or duties on Scottish or Welsh Ministers, or a person designated by them so that they have all of the powers or duties that they need to make this arrangement work.

894 Section 7A(12) 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 section, onwards, for example to the MHRA for the purposes of establishing a registry.

895 Section 7A(13) defines terms used in section 7A.

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

897 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.

898 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 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.

899 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.

900 Subsection (4) amends section 19 (medical devices: information systems) of the Medicines and Medical Devices Act 2021 as described below.

901 Subsection (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.

902 Subsection (4)(b) inserts a new subsection (7A) after section 19(7) that inserts the same provision as section 7A(12) into section 19, so allowing regulations to provide that a disclosure of information for the purposes of medical devices 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.

903 Subsection (5) amends section 43 (power to make consequential etc provision) of the Medicines and Medical Devices Act 2021. Where regulations made under sections 7A or 19 make consequential provision by virtue of section 43(2)(a), the new section 43(3) to 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 this Act. 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.

904 Subsection (6) amends section 44 (scope of Northern Ireland departments) of the Medicines and Medical Devices Act 2021 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.

905 Subsection (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. Subsection (7)(a) also provides a requirement for the appropriate authority to specifically consult Welsh and Scottish Ministers (as appropriate) on regulations under section 7A(1) if regulations concern Scotland or Wales.

906 Subsection (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.

907 Subsection (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 (the draft affirmative procedure).

908 Subsection (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 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

Section 102: Relevant bodies

909 This section sets out the "relevant bodies" to which the section applies. These are all health Non-Departmental Public Bodies and are as follows:

- Health Education England,
- the Health and Social Care Information Centre[14],
- the Health Research Authority,
- the Human Fertilisation and Embryology Authority,
- the Human Tissue Authority,
- NHS England.

910 The section then defines "Special Health Authorities" as those established under section 28 of the NHS Act 2006.

Section 103: Power to transfer functions between bodies

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

912 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 having regard to:

- efficiency;
- effectiveness;

[14] The Health and Social Care Information Centre is the legal name of NHS Digital.

- economy; and
- securing appropriate accountability to Ministers.

913 Subsection (3) sets out a restriction on the ability to transfer of functions of NHS England, in any case where the Secretary of State considers that such a transfer of functions would make NHS England redundant. The effect of this is that there will never be circumstances where the consequential power to abolish a body that has been rendered redundant due to a transfer of its functions, will be able to be used in respect of NHS England.

914 Subsection (4) sets out that where regulations are made under section 103 which include provision by virtue of section 183(1)(a), such provision 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. Subsection (1)(a) of section 103 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.

915 Subsection (5) sets out that where: any regulations made under section 103 contain provision which relates to a function that is exercisable in relation to Scotland, Wales or Northern Ireland, 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, and where the Secretary of State considers that the constitutional arrangements of the body to which the function is transferred do not contain corresponding provision as to membership, 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.

916 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".

Section 104: Power to provide for exercise of functions of Secretary of State

917 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.

918 Subsection (2) provides that the functions that may be specified are any 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.

919 Subsection (3) sets out that the regulations made under this section may make provision by virtue of section 183(1)(a) modifying the functions, constitutional or funding arrangements of the relevant bodies.

920 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 section 103.

921 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.

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

923 Subsection (7) states that "the health service" has the same meaning as in the NHS Act 2006. This defines "the health service" as follows:

> "the health service continued under section 1(1) of the National Health Service Act 2006 and under section 1(1) of the National Health Service (Wales) Act 2006".

Section 105: Scope of powers

924 Subsection (1) sets out what references in sections 103 and 104 to modifying the functions of a body include.

925 Subsection (2) sets out what references in sections 103 and 104 to the constitutional arrangements of a body include.

926 Subsection (3) sets out what references in sections 103 and 104 to modifying the funding arrangements of a body include.

927 Subsection (4) sets out certain types of powers that regulations under sections 103 and 104 may repeal and re-enact (but may not create), which are a power to make subordinate legislation, a power of forcible entry, search or seizure, and a power to compel the giving of evidence. Subsection (4) also provides that regulations under sections 103 and 104 may repeal and re-enact (but not create) a criminal offence.

928 Subsection (5) sets out that the provision made by regulations under sections 103 and 104 may repeal, revoke or amend provision made by or under an Act of Parliament.

929 Subsection (6) sets out that provision that may be made under sections 103 and 104 by virtue of section 183(1)(a) includes provision repealing, revoking or amending provision made by or under an Act, and legislation made by the Devolved Administration legislatures.

930 Subsection (7) sets out that "Minister" means a Minister of the Crown as defined by the Ministers of the Crown Act.

Section 106: Transfer schemes in connection with regulations

931 Subsection (1) sets out that the Secretary of State may make one or more schemes for the transfer of property, rights or liabilities in connection with regulations under section 103 or 104.

932 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.

933 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.

934 Subsection (4) sets out a non-exhaustive list of certain types of assets, rights and liabilities that may be included in a transfer.

935 Subsection (5) sets out a non-exhaustive list of types of provision that the transfer scheme may make.

936 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.

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

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

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

940 Subsection (10) lists those included in the term "appropriate person" as "any relevant body, the Secretary of State, an integrated care board, a Special Health Authority, or an NHS Trust".

Section 107: Transfer schemes: taxation

941 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 section 106, 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.

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

943 Subsections (5) states that references to the transfer of property in this section includes the grant of a lease.

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

Section 108: Consent and Consultation

945 Subsection (1) sets out the circumstances whereby the Secretary of State must obtain the consent of the Devolved Governments before making regulations under sections 103 and 104. This would be to:

a) obtain the consent of the Scottish Ministers in relation to any provision which would be within the legislative competence of the Scottish Parliament, if contained in an Act of that Parliament, and is not merely incidental to, or consequential on, provision which would be outside that legislative competence, or to any provision which modifies the functions of the Scottish Ministers;

b) obtain the consent of the Welsh Ministers in relation to any provision which would be within the legislative competence of Senedd Cymru, if contained in an Act of the Senedd, and is not merely incidental to, or consequential on, provision which would be outside that legislative competence, or to any provision which modifies the functions of the Welsh Ministers;

c) obtain the consent of a Northern Ireland department in relation to any provision which would be within the legislative competence of the Northern Ireland Assembly, if contained in an Act of that Assembly, and is not merely incidental to, or consequential on, provision which would be outside that legislative competence, or to any provision which modifies the functions of a Northern Ireland department.

Subsection (2) makes further provision clarifying the circumstances in which the consent of the relevant Northern Ireland department must be obtained under subsection (1). Consent will not be required in relation to a matter which 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 which does not affect, other than incidentally, a transferred matter (within the meaning of the Northern Ireland Act 1998).

946 Subsection (3) sets out that, before making regulations under section 103 or 104, the Secretary of State must consult:

i. any body to which draft regulations relate, and

ii. any other persons that the Secretary of State considers appropriate.

947 Subsection (4) sets out the requirement for the Secretary of State to carry out a further consultation should it appear appropriate to the Secretary of State, following a change to the draft regulations as a result of the initial consultation.

948 Subsection (5) states that for the purposes of this section it is immaterial whether the consultation is carried out before or after the commencement of the section.

Part 4: The Health Services Safety Investigations Body

Introductory

Section 109: Establishment of the HSSIB

949 This section establishes the Health Services Safety Investigations Body ("the HSSIB") as a body corporate. It also gives effect to Schedule 13.

Schedule 13: The Health Services Safety Investigations Body

Part 1 – Constitution

950 This part of 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 Investigator, and sets out the HSSIB's financial and reporting obligations.

Status

951 In Paragraph 1 of the Schedule 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

952 Paragraph 2 of the Schedule provides that 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.

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

The Chief Investigator: appointment and status

954 Paragraph 3 of the Schedule provides that 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 the HSSIB.

Other executive members: appointment and status

955 Paragraph 4 of the Schedule provides that the other 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

956 Paragraph 5 of the Schedule makes provision for some 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

957 Paragraph 6 of the Schedule applies where a non-executive member is suspended from office under paragraph 5(4). 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.

958 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.

959 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.

960 Paragraph 7 provides that 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, or the period ending with the revocation or expiry of the existing chair's suspension.

961 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 accordance with paragraph 7(2). The further term must begin at the end of their initial term as interim chair.

Non-executive members: payment

962 Paragraph 8 of the Schedule provides that the HSSIB must pay to non-executive members such remuneration as the Secretary of State may decide. The HSSIB must pay or make arrangements for the payment of pensions, allowances or gratuities as the Secretary of State may determine for any person who is or has been a non-executive member. If the Secretary of State decides there are exceptional circumstances which means that someone who is no longer a non-executive member should be compensated, the HSSIB must pay compensation to the person of such amount as the Secretary of State may determine.

Staff

963 Paragraph 9 of the Schedule provides that the HSSIB may 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

964 Paragraph 10 of the Schedule states that the HSSIB has the power to regulate its own procedure and any vacancy amongst the members does not affect the validity of its actions nor does a defect in the appointment of any member.

Committees

965 Paragraph 11 of the Schedule provides that the HSSIB may appoint committees and sub-committees and pay remuneration and allowances to committee members if they are not employees of the HSSIB.

Exercise of functions

966 Paragraph 12 of the Schedule provides that 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.

967 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

968 Paragraph 13 of the Schedule provides that the HSSIB can obtain assistance from other persons, for example experts, in exercising its functions.

Funding

969 Paragraph 14 of the Schedule provides that the Secretary of State may fund the HSSIB's activities to the extent that the Secretary of State considers appropriate.

Supplementary powers

970 Paragraph 15 of the Schedule provides that the HSSIB can do anything which will facilitate, or discharge any of its functions. This includes powers to enter into agreements, buy or sell property, supply goods and services and develop, own and exploit intellectual property. With consent of the Secretary of State, the HSSIB may temporarily borrow money by way of overdraft.

Use of income from charges

971 Paragraph 16 of the Schedule provides that any income that the HSSIB generates through imposing charges under sections 127(8) or 128(4) must be re-invested in carrying out those functions.

Losses and liabilities etc

972 Paragraph 17 of the Schedule provides that 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

973 Paragraphs 18 and 19 of the Schedule state that as a Non-Departmental Public Body, the HSSIB is required to keep proper accounts and prepare a set of accounts for each financial

year. The Secretary of State may direct the HSSIB as to the form, content, and methods and principles to be applied in the preparation of its accounts. 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

974 Paragraph 20 of the Schedule provides that 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 may also be required to provide further reports and information about the exercise of its functions to the Secretary of State, but not the details of specific investigations.

975 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

976 Paragraph 21 of the Schedule provides that 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

977 Paragraph 22 of the Schedule provides that the Secretary of State may make one or more transfer schemes in connection with the establishment of the HSSIB, to transfer to the HSSIB any property, rights or liabilities of NHS England relating to NHS England's functions pursuant to any directions made under section 44 of this Act, which are in force at the time the scheme is made.

978 Paragraph 23 of the Schedule provides that the Treasury may make regulations to vary the way in which a relevant tax has effect in relation to transfers under the scheme. This is a similar provision as can be seen elsewhere in the Act in respect of transfer schemes. The intention is that any transfer of assets, rights, or liabilities be tax neutral for NHS England and the HSSIB. This paragraph provides a power for the Treasury to vary any relevant tax in order to ensure that no taxes arise.

Investigations

Section 110: Investigation of incidents with safety implications

979 This section gives the HSSIB the function of investigating "qualifying incidents". These are incidents that 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 section 110(2)).

980 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 are to identify risks to the safety of patients and to address them by facilitating improvements in the health care system.

981 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 section 110(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 Service Act 2006. The HSSIB will determine and publish the criteria it will use to determine which qualifying incident it will investigate (under section 111(1)).

982 The aim is that the HSSIB will gather evidence which leads to systemic learning from investigating patient safety incidents and share these to prevent a recurrence of a similar incident elsewhere. The HSSIB will make recommendations in its reports 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. Section 110(4) provides that the HSSIB's investigations are 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.

Section 111: Deciding which incidents to investigate

983 This section outlines how the HSSIB determines which qualifying incidents it should investigate as part of its function under section 110. Section 111(2) also gives the Secretary of State the 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).

984 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 an NHS Trust or other healthcare provider.

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

986 If the HSSIB decides 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 an NHS 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.

Section 112: Criteria, principles and processes

987 This section 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 section 112(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 section 112(4)). The intention is that the HSSIB will make all necessary efforts to involve patients and families in investigations, as far as is reasonable andand practicable. 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.

988 Section 112(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.

989 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 section 112(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.

Reports

Section 113: Final reports

990 Section 113(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 section 110(3). This section 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.

991 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 section 110(4)).

992 Set out by section 113(5), protected material may be disclosed in the final report if the HSSIB determines that the benefits to patient 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.

993 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.

994 Where an investigation is carried out following a direction from the Secretary of State under section 111, the HSSIB must send a copy of the final report to the Secretary of State.

Section 114: Interim reports

995 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 section 110(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.

996 Interim reports are subject to the same conditions as final reports, as set out in section 113(3) to (7).

Section 115: Draft reports

997 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 section 115(1)(a));

ii. may send a draft report to any other person who the HSSIB believes should be provided with a draft (under section 115(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 section 115(3) and (4)).

Section 116: Response to reports

998 This section 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 section 115(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.

999 Section 226(4) 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.

Section 117: Admissibility of reports

1000 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.

1001 Set out by section 117(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.

1002 Section 117(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

Section 118: Powers of entry, inspection and seizure

1003 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, section 118(1)(a) gives the HSSIB powers to enter and inspect premises in England.

1004 These are similar powers to investigatory bodies in other safety-critical industries, such as the Air Accident Investigation Branch (AAIB).

1005 If a HSSIB investigator considers it necessary for the purposes of an investigation they 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).

1006 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 section 118(3)).

1007 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.

1008 If asked, an investigator must show evidence that they are acting on behalf of the HSSIB. This will normally be a letter of authority from the Chief Investigator.

1009 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.

1010 Section 118(5) provides that the HSSIB must give reasonable notice to the occupier of the premises before exercising its powers of entry, inspection and seizure if there is a Crown interest in the premises. This will allow arrangements to be made to ensure the safety of the HSSIB investigators and to maintain security at the premises being inspected.

1011 If the Secretary of State believes that it is appropriate and in the interests of national security, the powers conferred by 118(1) can be limited through issuing a certificate. In summary these are powers of entry, inspection and seizure. This limitation can include restricting the exercise of the powers in relating to land where there is a Crown interest (as 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 section 118(7).

Section 119: Powers to require information etc

1012 This section makes provision for an investigator to obtain information, documents, equipment or other items. An investigator may give a notice requiring 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.

1013 An investigator may only give a notice in certain circumstances, specified in 119(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 section 121. A person who commits this offence is liable on summary conviction to a fine.

1014 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.

1015 This section 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.

1016 An investigator may withdraw a notice issued under this section.

1017 This section 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.

1018 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.

Section 120: Voluntary provision of information etc

1019 This section 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 section 110. A disclosure authorised by this section does not breach any obligation of confidence owed by the person making the disclosure, or any other restriction on disclosure (section 113(1)).

Section 121: Offences relating to investigations

1020 This section creates new criminal offences for intentionally obstructing an investigator in the performance of functions conferred under section 118 (power of entry, inspection and

seizure), or failing to comply with a notice under section 119 without a reasonable excuse. For example, if an individual intentionally obstructed an inspector from entering and inspecting premises in England, this would be an offence. If a notice under section 119 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.

1021 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 section 121(2). 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.

1022 If a person relies on this defence, and there is evidence which raises issues with the defence, the court must presume that the defence is satisfied, until the prosecution proves beyond reasonable doubt that it is not.

1023 Section 121(5) sets out that a person who commits any of the offences will be liable on summary conviction to 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 or being liable upon summary conviction to a fine.

Protection of Material Held by the HSSIB

Section 122: Prohibition on disclosure of HSSIB material

1024 This section 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.

1025 Section 122(2) sets out that any information, documents, 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 (whether or not investigated by the HSSIB), and which has not been lawfully been made available to the public, is to be regarded as “protected material”. 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.

1026 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.

1027 Section 122(3) to (5) defines who the main prohibition on disclosure applies to. This includes 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

1028 Paragraph 1 of the Schedule provides that 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 authorised person reasonably believes that the disclosure is necessary for the purposes of carrying out the HSSIB's investigation function.

1029 In this context, "authorised person" means an individual who is connected with the HSSIB and authorised by the HSSIB for this purpose.

1030 Paragraph 2 of the Schedule provides that 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

1031 Paragraph 3 of the Schedule provides that 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 section under section 121 (offences relating to investigations) or under section 124 (offences of unlawful disclosure).

Disclosures relating to safety risks

1032 Paragraph 4 of the Schedule provides that 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.

1033 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 has evidence of negligent behaviour by a medical professional, which may risk the safety of patients and considers that the employer is able to take steps to address the risk it could only disclose information which is sufficient to enable the employer to take those steps e.g. perhaps to enable it to carry out their own investigation/internal process.

Disclosure by order of the High Court

1034 Paragraph 5 of the Schedule provides that 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.

1035 The HSSIB may make representations to the High Court if an application for disclosure is made.

1036 The High 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 of the safety of health care services provided to patients in England.

Exercise of Chief Investigator's functions

1037 Paragraph 6 of the Schedule 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

1038 Paragraph 7 provides that the HSSIB must publish 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. Any revised guidance must also be published.

Section 123: Exceptions of prohibition on disclosure

1039 This section specifies that the prohibition on disclosure set out in section 122(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 Part 4 of the Act, or regulations made by the Secretary of State, as set out in this section.

1040 This section provides for a regulation-making power for the Secretary of State. This allows for regulations to be made authorising the disclosure of protected materials. However, regulations may not authorise the disclosure of all protected material by reference to the incident to which it relates (subsection (3)).

Section 124: Offences of unlawful disclosure

1041 A person commits an offence if they breach the prohibition on disclosure of protected material held by the HSSIB (section 122(1)) by knowingly or recklessly disclosing protected material to another person, and they know or suspect that disclosure is prohibited..

1042 A person formerly connected with the HSSIB commits an offence if they breach the prohibition on disclosure under section 122(5) by knowingly or recklessly disclosing protected material to another person, and they know or suspect that disclosure is prohibited.

1043 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 section 123(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.

1044 A person who commits an offence under this section is liable on summary conviction to a fine.

Section 125: Restriction of statutory powers requiring disclosure

1045 This section prevents a power in any other legislation being used to require disclosure of, or to seize, any protected material from the HSSIB. Section 125(3) ensures that the section will not impact on any provision that is within the competence of a devolved legislature.

Relationship with other bodies

Section 126: Co-operation

1046 This section 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 (as defined at section 135);

m. the Health and Safety Executive;

n. the Commissioner for Patient Safety.

1047 Section 126(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.

Section 127: Assistance of NHS bodies

1048 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.

1049 The HSSIB may also give assistance to other persons not listed in subsection (2), 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.

1050 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.

Section 128: Investigations relating to Wales and Northern Ireland

1051 Section 128 allows the HSSIB to enter into an agreement with a person to carry out an investigation in the UK if the investigation falls within subsection (2). That subsection requires, amongst other things, for the investigation to be into one or more incidents that have occurred or are occurring in the UK during the provision of services provided as part of the health service in Wales or health care in Northern Ireland (as defined at subsection (3) or on premises where those services are provided). The investigations will be similar to other HSSIB investigation in that they will not involve the assessment or determination of blame or civil or criminal liability but they will not benefit from protected information or other investigatory powers which apply to the HSSIB's investigation function. These investigations can be charged for (subsection (4)) but the HSSIB cannot make a profit as the charges must not exceed the costs incurred by it (subsection (5)). This is a secondary function of the HSSIB and so agreements cannot be entered into under this section if they will, to a significant extent, interfere with the exercise of the HSSIB and its investigation function (subsection (6)).

1052 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.

1053 The HSSIB cannot contract to provide such investigations in respect of Scottish Health care but bodies in Scotland may request expertise from HSSIB under section 127 during the course of its own investigation.

Oversight of functions

Section 129: Failure to exercise functions

1054 This section provides for intervention by the Secretary of State should the HSSIB fail significantly to carry out its functions (which includes failing to carry them out properly). In that event, the section 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.

Section 130: Review

1055 This section confers a duty on the Secretary of State to review the effectiveness of the HSSIB in exercising its investigation function, to prepare and publish a report of that review, and to lay the report before Parliament. This must be done before the end of the four years following the section of the Act which establishes the investigation function (section 110) coming into force.

Offences: supplementary

Section 131: Offences by bodies corporate

1056 This section deals with corporate liability. If an offence under Part 4 of the Act 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.

Section 132: Offences by partnerships

1057 This section 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 partnership as well as the individual partners.

1058 If an offence under Part 4 of the Act 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.

1059 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.

1060 For the purposes of proceedings, Schedule 3 of the Magistrates' Courts Act 1980 applies as it applies in relation to a body corporate.

Supplementary

Section 133: Obligations of confidence etc

1061 Any disclosure of information, document, equipment, or other item which is required or authorised by section 119, section 120 or Schedule 14 does not breach any obligation of confidence owed by the person making the disclosure or any other restriction on disclosure.

1062 Nothing within Part 4 of the Act requires or authorises a disclosure of information which would contravene data protection legislation. However, when considering whether a disclosure would breach data protection legislation, any requirement or authorisation to make such a disclosure under the Act should be taken into account.

Section 134: Consequential amendments relating to Part 4

1063 This section inserts Schedule 15, which makes consequential amendments in relation to the HSSIB.

Schedule 15: Consequential Amendments relating to Part 4

1064 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.

Section 135: Interpretation of Part 4

1065 This section provides definitions that apply throughout Part 4 of the Act.

Part 5: Virginity Testing and Hymenoplasty Offences

Virginity testing offences: England and Wales

Section 136: Offence of virginity testing: England and Wales

1066 Section 136(1) makes it an offence under the law of England and Wales for a person to carry out virginity testing. The person must either be in England and Wales or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in England and Wales. The victim of the testing does not need to be a United Kingdom national or resident.

1067 Section 136(2) defines virginity testing as the examination of female genitalia, with or without consent, for the purpose (or purported purpose) of determining virginity. As it is not in fact possible to determine whether a woman or girl has ever had sexual intercourse by examining their genitalia, the person carrying out the testing would either have the belief that they could make such a determination from the examination, or making such a determination would be the ostensible reason for carrying out the test. The purpose, or purported purpose, which the person carrying out the test has is the *mens rea*, or mental element, of the offence.

1068 There is no reliable way of establishing virginity, nor is there any clinical reason to know if a woman or girl is a virgin. As such, the purpose of a healthcare, safeguarding or forensic examination would never be to establish virginity or otherwise, and a defence to this effect has therefore not been included in the offence.

1069 "United Kingdom national" is defined in Section 136(4).

1070 Section 136(5) defines "female genitalia" as a vagina or vulva.

Section 137: Offence of offering to carry out virginity testing: England and Wales

1071 Section 137(1) makes it an offence:

a. For a person in England and Wales to offer to carry out virginity testing in the UK, or to make an offer to carry out testing which has a sufficient jurisdictional connection, or

b. A UK national or habitual resident of England and Wales to make an offer to carry out virginity testing anywhere.

1072 Offering is included as a separate offence, so that people who are offering the service can be prevented from going ahead with testing and potential victims can be protected. Section 137(2) states that virginity testing has "sufficient jurisdictional connection" for the purposes of subsection (1)(a) if it is carried out on (a) a UK national, or (b) someone who is habitually resident in the UK.

1073 Subsection (3) gives the same meaning to "United Kingdom National" as section 136(4) and virginity testing has the meaning given by section 136(2).

Section 138: Offence of aiding or abetting etc a person to carry out virginity testing: England and Wales

1074 Section 138(1) makes it an offence under the law of England and Wales for a person who is in England and Wales, or a person outside England and Wales but who is a United Kingdom national or habitually resident in England and Wales, to aid or abet, counsel or procure the commissioning of virginity testing which has a sufficient jurisdictional connection. Subsection (2) defines this as the person being tested being in the United Kingdom or being a UK national or habitual resident.

1075 This offence would cover the case where, for example, a father makes arrangements from within England and Wales for the testing of his (UK national or habitual resident) daughter to take place overseas. It would also cover the case where, for example, a woman makes arrangements from England for her niece (not a UK national or habitual resident) to be tested in Scotland, while she remains in England. It would also be an offence for a parent (a UK national or habitual resident of England and Wales) who travels overseas with their daughter to make arrangements for, or assist with, the testing of their daughter while there, provided she is also a UK national or habitual resident.

1076 This offence is primarily aimed at the case where the person carrying out the test is outside the UK and is not a UK national or habitual resident. If they were a UK national or habitual resident, they would be guilty of an offence under section 136, and a UK national or habitual resident of England and Wales who aids and abets, or encourages or assists, that offence would be liable under existing inchoate offences, including if they were outside the UK. But as it might be difficult to establish the nationality or habitual residence of the person carrying out the test, the offence does not depend on the tester being a foreign national. Subsection (3) makes it clear that the inclusion of these offences does not affect the existing rules on secondary liability in relation to the main offence of virginity testing.

Section 139: Virginity testing offences in England and Wales: penalties

1077 Section 139(1) deals with the mode of trial and maximum penalties for the new offences in England and Wales. They are triable either way and carry a maximum 5-year custodial sentence on indictment and an unlimited fine, or both.

1078 The maximum sentence reflects the long-term physical and psychological detrimental effects virginity testing can have on the victim.

1079 Section 139(2) refers to the length of imprisonment for a summary only conviction, which is currently 6 months in England and Wales. Paragraph 24(2) of Schedule 22 to the Sentencing Act 2020[15] increases the magistrate courts' powers to impose imprisonment from 6 months to 12 months. This has yet to be commenced. Once it is commenced, a summary only conviction of a virginity test tried in a magistrate's court will be able to carry the maximum prison sentence of 12 months.

[15] Sentencing Act 2020 (legislation.gov.uk)

Virginity testing offences: Scotland

Section 140: Offence of virginity testing: Scotland

1080 Section 140(1) makes it an offence under the law of Scotland for a person to carry out virginity testing. The section replicates the England and Wales offence in section 136 for Scotland, so that the person must either be in Scotland or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in Scotland.

Section 141: Offence of offering to carry out virginity testing: Scotland

1081 Section 141(1) replicates section 137 for Scotland, so that it is an offence:

a. For a person in Scotland to offer to carry out virginity testing in the UK, or to make an offer to carry out testing which has a sufficient jurisdictional connection (as defined in section 141(2)), or

b. A national of the United Kingdom or habitual resident of Scotland to make an offer to carry out virginity testing anywhere.

Section 142: Offence of aiding or abetting etc a person to carry out virginity testing: Scotland

1082 Section 142(1) replicates for Scotland the England and Wales offence of aiding or abetting etc the carrying out of virginity testing, so that it will be an offence under the law of Scotland for a person who is in Scotland, or a person outside Scotland but who is a United Kingdom national or a habitual resident of Scotland, to aid, abet, counsel, procure or incite the carrying out of virginity testing that has a sufficient jurisdictional connection (as defined in section 142(2)).

Section 143: Virginity testing offences in Scotland: penalties and supplementary

1083 Section 143(1) deals with the mode of trial and maximum penalties for the new offences in Scotland (sections 140, 141 and 142). They carry a maximum summary custodial sentence of 12 months or a maximum 5-year custodial sentence on indictment or an unlimited fine or both. The maximum sentence reflects the long-term physical and psychological detrimental effects virginity testing can have on the victim.

1084 Section 143(2) provides that a person committing the virginity testing offence outside of Scotland may be prosecuted, tried and punished for the offence in (a) a sheriff court district where they are apprehended or in custody or (b) a sheriff court district where the Lord Advocate decides.

Virginity testing offences: Northern Ireland

Section 144: Offence of virginity testing: Northern Ireland

1085 Section 144(1) makes it an offence under the law of Northern Ireland for a person to carry out virginity testing. The section replicates the England and Wales offence in section 136 for Northern Ireland, so the person must either be in Northern Ireland or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in Northern Ireland.

Section 145: Offence of offering to carry out virginity testing: Northern Ireland

1086 Section 145(1) replicates section 137 for Northern Ireland, so that it is an offence:

a. For a person in Northern Ireland to offer to carry out virginity testing in the UK, or to make an offer to carry out testing which has a sufficient jurisdictional connection (as defined in section 145(2)), or

b. A national of the United Kingdom or habitual resident of Northern Ireland to make an offer UK to carry out virginity testing anywhere.

Section 146: Offence of aiding or abetting etc a person to carry out virginity testing: Northern Ireland

1087 Section 146(1) replicates for Northern Ireland the England and Wales offence of aiding or abetting etc the carrying out of virginity testing, so that it will be an offence under the law of Northern Ireland for a person who is in Northern Ireland, or a person outside Northern Ireland but who is a United Kingdom national or a resident in Northern Ireland, to aid, abet, counsel or procure the carrying out of virginity testing that has sufficient jurisdictional connection (as defined in section 146(2)).

Section 147: Virginity testing offences in Northern Ireland: penalties

1088 This section deals with the mode of trial and maximum penalties for the new offences in Northern Ireland. They are triable either way and carry a maximum 5-year custodial sentence on indictment or an unlimited fine, or both.

1089 The maximum sentence reflects the long-term physical and psychological detrimental effects virginity testing can have on the victim.

Hymenoplasty Offences: England and Wales

Section 148: Offence of carrying out hymenoplasty: England and Wales

1090 Section 148(1) makes it an offence under the law of England and Wales for a person to carry out hymenoplasty. The person must either be in England and Wales or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in England and Wales (subsection (3)). The victim of the hymenoplasty does not need to be a United Kingdom national or resident.

1091 Subsection (2) of section 148 defines hymenoplasty as the reconstruction of the hymen, with or without consent. The expert panel were clear that the benefits of an outright ban outweigh any argument that women and girls' autonomy is undermined by no longer having access to the procedure.

1092 The expert panel confirmed that there is never a medical or clinical need to reconstruct the hymen. As such, a defence to this effect has not been included in the offence.

1093 "United Kingdom national" is defined in subsection (4).

Section 149: Offence of offering to carry out hymenoplasty: England and Wales.

1094 Section 149(1) makes it an offence:

(a) for a person in England and Wales to offer to carry out hymenoplasty in the UK, or to make an offer to carry out hymenoplasty which has a "sufficient jurisdictional connection", or

(b) for a UK national or habitual resident of England and Wales to make an offer to carry out hymenoplasty anywhere.

1095 Offering is included as a separate offence, so that people who are offering the service can be prevented from going ahead with the procedure and potential victims can be protected. It will also give effect to the expert panel's recommendation that the advertising of hymenoplasty be banned, because a person who arranges for an advertisement to be published offering their hymenoplasty services would be making an offer. Subsection (2) states that hymenoplasty has "sufficient jurisdictional connection" for the purposes of subsection (1)(a) if it is carried out on a (a) UK national, or (b) someone who is habitually resident in the UK.

1096 Subsection (3) gives the same meaning to "United Kingdom National" as section 148(4) and hymenoplasty has the meaning given by section148(2).

Section 150: Offence of aiding or abetting etc a person to carry out hymenoplasty: England and Wales

1097 Section 150(1) makes it an offence under the law of England and Wales for a person who is in England and Wales, or a person outside England and Wales but who is a United Kingdom national or habitually resident in England and Wales, to aid or abet, counsel or procure the carrying out of hymenoplasty which has a sufficient jurisdictional connection. Subsection (2) defines this connection as the person undergoing the procedure either being in the United Kingdom or being a UK national or habitual resident.

1098 This offence would cover the case where, for example, a father makes arrangements from within England and Wales for his (UK national or habitual resident) daughter to have the procedure overseas. It would also cover the case where, for example, a woman makes arrangements from England for her niece (not a UK national or habitual resident) to have the procedure in Scotland, while she remains in England. It would also be an offence for a parent (a UK national or habitual resident of England and Wales) who travels overseas with their daughter, and who makes the arrangements for, or assists with, their daughter undergoing the procedure while there, provided she is also a UK national or habitual resident.

1099 This offence is primarily aimed at the case where the person carrying out procedure is outside the UK and is not a UK national or habitual resident. If they were a UK national or habitual resident, they would be guilty of an offence under section 148, and a UK national or habitual resident of England and Wales who aids and abets, or encourages or assists, that offence would be liable under existing inchoate offences, including if they were outside the UK. But as it might be difficult to establish the nationality or habitual residence of the person carrying out the hymenoplasty, the offence does not depend on the person carrying out the procedure being a foreign national. Subsection (3) makes it clear that the inclusion of these offences does not affect the existing rules on secondary liability in relation to the main offence of hymenoplasty.

Section 151: Hymenoplasty offences in England and Wales: Penalties

1100 Section 151(1) deals with the mode of trial and maximum penalties for the new offences in England and Wales. They are triable either way and carry a maximum 5 year custodial sentence on indictment or an unlimited fine, or both.

1101 The maximum sentence reflects the long-term physical and psychological detrimental effects hymenoplasty can have on the victim.

1102 Subsection (2) refers to the length of imprisonment for a summary only conviction, which is currently 6 months in England and Wales. Paragraph 24(2) of Schedule 22 to the

Sentencing Act 2020[16] increases the magistrate courts' powers to impose imprisonment from 6 months to 12 months. This has yet to be commenced. Once it is commenced, a summary only conviction of hymenoplasty tried in a magistrate's court will be able to carry the maximum prison sentence of 12 months.

Hymenoplasty offences: Scotland

Section 152: Offence of carrying out hymenoplasty: Scotland

1103 Section 152(1) makes it an offence under the law of Scotland for a person to carry out hymenoplasty. The section replicates the England and Wales offence in section 148 for Scotland, so that the person must either be in Scotland or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in Scotland.

Section 153: Offence of offering to carry out Offering hymenoplasty: Scotland

1104 Section 153(1) replicates section 149(1) for Scotland, so that it is an offence:

(a) for a person in Scotland to offer to carry out hymenoplasty in the UK, or to make an offer to carry out the procedure which has a sufficient jurisdictional connection (as defined in section 153(2)), or

(b) for a national of the United Kingdom or habitual resident of Scotland to make an offer to carry out hymenoplasty anywhere.

Section 154: Offence of aiding or abetting etc a person to carry out hymenoplasty: Scotland

1105 Section 154(1) replicates for Scotland the England and Wales offence of aiding or abetting etc. the carrying out of hymenoplasty (section 150), so that it will be an offence under the law of Scotland for a person who is in Scotland, or a person outside Scotland, but who is a United Kingdom national or a habitual resident of Scotland, to aid, abet, counsel, procure or incite the carrying out of hymenoplasty that has a sufficient jurisdictional connection (as defined in section 154(2)).

Section 155: Hymenoplasty offences in Scotland: penalties and supplementary penalties

1106 Section 155(1) details the mode of trial and maximum penalties for the new offences in Scotland. They carry a maximum summary custodial sentence of 12 months or a maximum 5 year custodial sentence on indictment or an unlimited fine or both. The maximum sentence reflects the long-term physical and psychological detrimental effects hymenoplasty can have on the victim.

1107 Subsection (2) provides that a person committing the hymenoplasty offence outside of Scotland may be prosecuted, tried and punished for the offence in a sheriff court district where they are (a) apprehended or in custody or (b) a sheriff court district where the Lord Advocate decides.

Hymenoplasty offences: Northern Ireland

Section 156: Offence of carrying out hymenoplasty: Northern Ireland

1108 Section 156(1) makes it an offence under the law of Northern Ireland for a person to carry out hymenoplasty. The section replicates the England and Wales offence in section 148

[16] Sentencing Act 2020 (legislation.gov.uk)

for Northern Ireland, so that the person must either be in Northern Ireland or, if the person is outside the United Kingdom, they must be a United Kingdom national or habitually resident in Northern Ireland.

Section 157: Offence of offering to carry out hymenoplasty: Northern Ireland

1109 Section 157(1) replicates section 149(1) for Northern Ireland, so that it is an offence:

(a) for a person in Northern Ireland to offer to carry out hymenoplasty in the UK, or to make an offer to carry out the procedure which has a sufficient jurisdictional connection, or

(b) for a national of the United Kingdom or habitual resident of Northern Ireland to make an offer to carry out hymenoplasty anywhere.

Section 158: Offence of aiding or abetting etc a person to carry out hymenoplasty: Northern Ireland

1110 Section 158(1) replicates for Northern Ireland the England and Wales offence of aiding or abetting etc. the carrying out of hymenoplasty (section 150), so that it will be an offence under the law of Northern Ireland for a person who is in Northern Ireland, or a person outside Northern Ireland, but who is a United Kingdom national or a habitual resident of Northern Ireland, to aid, abet, counsel or procure the carrying out of hymenoplasty that has a sufficient jurisdictional connection (as defined in section 158(2)).

Section 159: Hymenoplasty offences in Northern Ireland: Penalties

1111 Section 159 deals with the mode of trial and maximum penalties for the new offences in Northern Ireland. They are triable either way and carry a maximum 5 year custodial sentence on indictment or an unlimited fine, or both.

1112 The maximum sentence reflects the long-term physical and psychological detrimental effects hymenoplasty can have on the victim.

Consequential Amendments

Section 160: Consequential amendments relating to Part 5

1113 Section 160 introduces Schedule 16, which contains some consequential amendments to other legislation in connection with the creation of the new offences of carrying out, offering and aiding or abetting etc virginity testing and hymenoplasty.

Schedule 16: Virginity testing and hymenoplasty: consequential amendments

1114 The new offences for England and Wales are inserted into section 65A of the Police and Criminal Evidence Act 1984 and the offences for Northern Ireland are inserted into Article 53A of the Police and Criminal Evidence (Northern Ireland) Order 1989 by paragraphs 1 and 2 of this Schedule. Additional powers, such as in relation to taking and retaining samples such as fingerprints and DNA, are available for investigations into the offences listed in these provisions. A similar amendment is made in relation to Scotland, by adding the Scottish offences to section 19A of the Criminal Procedure (Scotland) Act 1995 (paragraph 5 of this Schedule). Paragraph 3 also inserts the new offences at paragraph 25A (England and Wales), 43A (Scotland) and 68 (Northern Ireland) of Schedule 7A to the Criminal Justice and Public Order Act 1994. This section lists the offences for which cross-border powers of arrest are available.

1115 The new offences for England and Wales are inserted into section 51C of the Crime and Disorder Act 1998 (paragraph 7 of the Schedule). This would enable virginity testing and

hymenoplasty cases involving children to be taken over and proceeded with without delay by the Crown Court where the Director of Public Prosecutions gives a notice. An amendment concerning procedural matters for the new offences is made in relation to Scotland by adding the Scottish offences to section 271BZA of the Criminal Procedure (Scotland) Act 1995 (paragraph 6 of this Schedule). This would enable evidence to be given in advance by children in solemn cases.

- An amendment is made in relation to Scotland by adding the Scottish offences to Schedule 1 to the Protection of Vulnerable Groups (Scotland) Act 2007 (paragraph 8 of this Schedule). This amendment relates to vetting and barring of individuals who work with children and vulnerable adults, and is temporary, pending the repeal of the relevant provisions by the Disclosure (Scotland) Act 2020.

1116 The new offences for England and Wales are also inserted into Schedule 4 to the Modern Slavery Act 2015 (paragraph 9 of the Schedule) meaning that a victim of trafficking or exploitation will not have the automatic defence in section 36B of the 2015 Act in relation to a virginity testing or hymenoplasty offence.

Part 6: Miscellaneous

Pharmaceutical services

Section 161: Pharmaceutical services: remuneration in respect of vaccines etc

1117 Subsections (1) and (2) amend Section 164 of the NHS Act 2006 and Section 88 of the National Health Service (Wales) Act 2006 respectively to amend the powers that enable regulations to be made to establish different payment arrangements for special medicinal products (compared to other medicinal products) to include vaccines and immunisations, medicines or drugs used for preventing or treating pandemic or potential pandemic diseases, and associated products. The regulations could include, for example, calculation of remuneration by means of obtaining quotes, but most significantly, in practice, they could provide for circumstances where remuneration would not be provided, in particular where products were centrally procured.

1118 Subsection (1)(a) substitutes for "special medicinal products", previously the only type of product for which regulations could provide for different payment arrangements, a list comprising the following:

- Drugs or medicines that can be used for the purposes of vaccination or immunisation of people against disease; and any products that may be used in connection with the supply or administration of such drugs or medicines.
- Other drugs or medicines that may be used for preventing or treating a disease which at the time regulations are made the Secretary of State considers to be either a pandemic disease or at risk of becoming a pandemic disease; and anything used in connection with the supply or administration of such drugs or medicines.
- A special medicinal product, which is an unlicensed medicinal product supplied as outlined in regulation 167 of the Human Medicines Regulations 2012.

1119 Subsection (1)(b) makes amendments consequential to the new list outlined in subsection (1)(a).

1120 Subsection (1)(c) removes the definition of special medicinal product from subsection (8E) of section 164 as this is now included in the list at new subsection (8A)(e).

1121 For England, subsection (1)(d) specifies that where regulations are made with respect to medicines or drugs that are used for preventing or treating a disease which the Secretary of State considers to be either a pandemic disease or at risk of becoming a pandemic disease the Secretary of State must revoke the regulations within such a period as the Secretary of State considers reasonable, once the disease to which the measures relate is no longer pandemic or at risk of becoming pandemic.

1122 Subsection (2) replicates subsection (1) provisions regarding England for Wales, by amendment of section 88 of the National Health Service (Wales) Act 2006. Explanations for subsections (2)(a)-(2)(c) are consistent with those for subsections (1)(a)-(1)(c) outlined above. The only exception is regarding (2)(d) where Welsh Ministers, rather than the Secretary of State, are responsible for deciding that what they consider a pandemic disease or a disease at risk of becoming a pandemic disease is no longer in this category, at which point measures relating to medicines or drugs used for preventing or treating the disease must be revoked within such period as the Welsh Ministers consider reasonable.

International Healthcare

Section 162: International Healthcare arrangements

1123 This section amends the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 ("HEEASAA") to enable the Government and the Devolved Authorities to implement comprehensive reciprocal healthcare agreements with countries outside the EEA and Switzerland.

1124 Subsections (1) and (7) change the title of the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 to the Healthcare (International Arrangements) Act 2019 (HIAA)so it is clear that the legal framework for implementing comprehensive healthcare arrangements in the Act is no longer restricted to arrangements with the EEA and Switzerland.

1125 Subsections (3) and (4) remove 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 replace them with a healthcare agreements and payments discretionary regulation-making power. The previous powers were created to support people to access healthcare in the EEA and Switzerland in the event of leaving the EU without an agreement. As the UK Government has now agreed social security coordination provisions covering healthcare in the EU in the Withdrawal Agreement and the Trade and Cooperation Agreement, these measures are no longer needed. The UK Government has also reached an agreement with Switzerland to continue reciprocal healthcare provisions.

1126 The amendments provide the Secretary of State (new section 2(1) HIAA) and the devolved authorities (new section 2A(1) HIAA) with a power to make regulations (subject to draft affirmative procedure) that make provision for the purpose of giving effect to a healthcare agreement, including provision about payments.

1127 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) HIAA). This discretionary power, could, for example, be exercised to pay for a specific, urgent treatment which falls marginally outside the scope of an agreed healthcare agreement.

1128 New sections 2(4) and 2(5) HIAA set out certain provision that may be under the regulations. Section 2(4) states that regulations made under section 2 may include provision about administrative arrangements (including evidential requirements). Section 2(5) states that regulations made under new section 2 HIAA are capable of being used to confer or delegate functions to a "relevant public authority" (which is defined at new section 2(7) HIAA) and Scottish and Welsh health boards.

1129 New section 2A(2) and (4) HIAA describe the circumstances in which a devolved authority (defined in new section 2A(3) HIAA as the Scottish Ministers, Welsh Ministers and a Northern Ireland department) can use the power in section 2A(1) HIAA to make regulations. New section 2A(2) HIAA provides that a devolved authority may not make provision under section 2A(1) unless the provision is within the devolved authority's competence. Devolved competence is defined at new section 2A(4) HIAA.

1130 Among other things, regulations made under new section 2A HIAA are capable of being used to confer or delegate functions to a "public authority" (section 2A(6) HIAA) which is defined at new section 2A(8) HIAA.

1131 New section 2B HIAA sets out that consent of a Minister of the Crown is required if a Devolved Authority is making a provision using the power in new section .2A HIAA and the provision, if contained in primary legislation made by the devolved legislatures, would require the consent of a Minister of the Crown. That could be where the relevant devolved legislature's legislative powers were subject to a consent requirement, or where the devolved authority would normally require consent to make such a provision via secondary legislation. This requirement for consent will not apply if the devolved authority already has power to make such provision using secondary legislation without needing the consent of the Minister of the Crown.

1132 Subsection (5) amends the definition of "healthcare agreement" in section 3 of HIAA so that it is clear it includes any agreement regarding healthcare provided in another country or territory outside of the UK, whether payments are included in the agreement or not.

1133 Subsection (6) amends the regulations and directions section of HIAA (section 7) to reflect the existence of the new regulation-making powers and ensure that they are subject to the draft affirmative procedure.

1134 The territorial extent and application of this section is England and Wales, Scotland and Northern Ireland.

Social Care: Regulation and Financial Assistance

Section 163: Regulation of local authority functions relating to adult social care

1135 This section 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.

1136 Section 46A(1) will require the CQC to review local authorities' undertaking of "regulated care functions" (prescribed 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.

1137 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.

1138 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 (section 46A(5)). 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.

1139 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.

1140 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 in new section 46A(12) 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.

1141 Subsection (4) amends section 48 so that reviews under 46A are excluded from constituting a special review under that section.

1142 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 the local authority is failing to discharge any of its adult social services functions to an acceptable standard.

1143 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.

Section 164: Default powers of Secretary of State in relation to adult social care

1144 Subsection (1) amends Section 7D of the Local Authority Social Services Act 1970.

1145 Under section 7D of the Local Authority Social Services Act 1970, where the Secretary of State is satisfied that any local authority has failed – without a reasonable excuse – to comply with any of their duties that are social service functions (other than certain specified functions), the Secretary of State may make an order containing directions to the local authority for the purpose of ensuring the duty is complied with. Subsection (1) takes duties imposed by or under Part 1 of the Care Act 2014 out of scope of the powers conferred by section 7D.

1146 Subsection (2) makes provision to amend the Care Act 2014. Subsection (3) inserts sections 72A and 72B into the Care Act 2014.

1147 Under section 72A(1), where the Secretary of State considers that a local authority is failing, or has failed, to discharge its duties under Part 1 of the Care Act 2014 to an acceptable standard, the Secretary of State may issue directions to the local authority for the purpose of addressing the failure.

1148 Under section 72A(2), directions may:

a. require the local authority to co-operate with advice given by the Secretary of State or their nominee;

b. require the local authority to collaborate with the Secretary of State or their nominee in taking steps specified in the directions; or

c. require the local authority to provide information required either by the Secretary of State or their nominee.

1149 Under section 72A(3), where necessary for addressing the failure, directions may provide for specified adult social care functions of the local authority to be carried out by the Secretary of State or their nominee.

1150 Under section 72A(7) the local authority may be required by the directions to financially remunerate the Secretary of State or their nominee for costs they have incurred as a consequence of the directions.

1151 In accordance with section 72A(4), where the Secretary of State or their nominee have taken over the running of adult social care functions under subsection (3), where appropriate a reference to a local authority in legislation or other documents is to be read as a reference to the Secretary of State or their nominee.

1152 In accordance with section 72A(5), where directions given under section 72A(3) expire or are revoked and not replaced, a reference in any instruments or other documents to the Secretary of State or their nominee is to be read as a reference to the local authority to whom the directions were issued.

1153 Under section 72A(6), where the Secretary of State has taken over the running of any adult social services following directions made under subsection (3), they may by regulations disapply or modify legislation which gives the Secretary of State a function in relation to a function of a local authority. For example, under section 40 of the Care Act 2014 the Secretary of State is responsible for resolving ordinary residence disputes. It may not be appropriate for the Secretary of State to perform this role if the Secretary of State is also exercising adult social care functions of one of the LAs involved.

1154 Section 72B makes supplementary provisions in relation to directions made under section 72A.

a. The Secretary of State must give the local authority an opportunity to make representations on draft directions, except where the Secretary of State considers that for reasons of urgency it is not practical to do so (section 72B(1)).

b. The Secretary of State may change or revoke the directions by issuing further directions (section 72B(2)). Where the Secretary of State considers variations not to be significant, the duty in subsection (1) to allow local authorities to make representations does not apply (section 72B(3)).

c. The Secretary of State must issue directions to the local authority in writing (section 72B(4)). The Secretary of State must publish their directions, and the reasons for issuing them (72B(5)).

d. The Secretary of State can seek to enforce directions by applying for a court order (section 72B(6)).

1155 Subsection (4) amends section 125(4) of the Care Act 2014 to provide for the procedure by which regulations made under section 72A(6) are made (draft affirmative).

Section 165: Care Quality Commission's powers in relation to local authority failings

1156 This section amends section 50 of the Health and Social Care Act 2008 to provide that:

a. The CQC is required to notify the Secretary of State wherever it identifies that a local authority is failing to discharge its duties to an acceptable standard, and to recommend next steps it considers the Secretary of State should take (subsection (2)).

b. The CQC's power to give a notice to a local authority where it considers the failure is not substantial is removed.

1157 This section also clarifies that CQC may specify failures and provide recommendations to the local authority in its reports (new subsection (3A) of section 50, as inserted by subsection (3)(b)).

Section 166: Cap on care costs for charging purposes

1158 Subsection (1) sets out that the Care Act 2014 is to be amended.

1159 Subsection (2) makes amendments to section 15 of the 2014 Act meaning the costs that accrue towards the cap on care costs are the costs the adult is required to pay (at the local authority rate) rather than the combined costs incurred by both the adult and the local authority.

1160 Section 15(2) and (3) of the 2014 Act is substituted by a new subsections (2) to (3B) to specify what costs incurred in meeting eligible care and support needs can count towards the cap on care costs:

- Where a local authority is meeting eligible needs, the amount the adult was required to pay accrues towards the cap, at a local authority determined rate, which is set out in a personal budget.
- Where a local authority is not meeting eligible needs, the rate of spend that accrues towards the cap will be set out in either an adult's personal budget (section 26(2A)(a) of the 2014 Act) or an independent personal budget.

1161 The new subsection (3) confirms any reference to "eligible needs" does not include any eligible needs prior to when a Personal Budget or Independent Personal Budget is in place, other than the period of time between the individual making the request for the Personal Budget or Independent Personal Budget, or while it is being prepared, and it being put in place.

1162 The new subsection (3A) includes a new definition of the term "eligible needs" in section 15 of the 2014 Act and the new subsection (3B) is a new definition of "responsible local authority". Both of these definitions apply across Part 1 of the 2014 Act.

1163 Subsection (3) amends section 24 of the 2014 Act (the steps for the local authority to take) by substituting subsection (3) of that section, which sets out the steps to be taken by a local authority where none of an adult's eligible care needs are being met by a local authority. This provides a duty for the responsible local authority to prepare an Independent Personal Budget, which is used to determine the rate the adult will accrues towards the cap.

1164 Subsection (4) amends section 26 (personal budget) of the 2014 Act to require specific information on the needs a local authority is meeting and how costs are apportioned and then charged to an adult, to be set out in a personal budget. If eligible needs are being met by a local authority, there is also a requirement for the personal budget to include the cost of meeting those needs at the local authority rate, how much the adult must pay towards that cost and any daily living costs, if appropriate. In addition, if the adult has other eligible needs which are not being met by a local authority, the local authority must include in the personal budget what the cost of meeting those needs would be at the responsible local authority's rate and any daily living costs, if appropriate.

1165 Subsection (5) amends section 28 of the 2014 Act (independent personal budget) to provide that an independent personal budget specifies what the cost of meeting an adult's eligible needs during a relevant period at the responsible local authority determined rate would be.

1166 Subsection (6) amends section 29 (care account) to prevent duplication and refer to the new definition of "responsible local authority", as inserted by subsection (2) of this section.

1167 Subsections (7) and (8) amend Section 31 (adults with capacity to request direct payments) and 32 (adults without capacity to request direct payments) of the 2014 Act respectively, to clarify that, where the personal budget includes both eligible needs to be met by the local authority and eligible needs that the local authority is not meeting (as provided

for in the amendments to section 26 of the 2014 Act set out in subsection (4)), the request for a direct payment can only apply to those needs the local authority must or chooses to meet under section 24(1) of the 2014 Act.

1168 Subsection (9) amends section 37(15)(a) of the 2014 Act (notification, assessment etc.) to omit a definition of "eligible needs" as a new definition of "eligible needs" has been inserted for the purposes of Part 1 of the 2014 Act into section 15 of the 2014 Act by subsection (2) of this section.

1169 Subsection (10) inserts new locations of definitions for "eligible needs" and "the responsible local authority" into section 80 of the 2014 Act to aid interpretation of that Act.

Section 167: Provision of social care services: financial assistance

1170 This Section amends sections 149 to 153 of the Health and Social Care Act 2008 ("the 2008 Act").

1171 This section inserts new subsections (1A) and (1B) to section 149. These provisions set out a new power for the Secretary of State to provide financial assistance to any bodies engaged in the provision of social care services, or the provision of services connected with those social care services, if those social care services are provided in England.

1172 The section replaces section 153 of the 2008 Act, enabling the Secretary of State to direct certain bodies to exercise their functions to provide financial assistance to bodies engaged in providing social care and health services (or providing services connected with the provision of those services) under section 149(1) and new section 149(1A).

1173 The new section 153(3) also allows the Secretary of State to direct either a National Health Service trust or a Special Health Authority to exercise the power in section 149(2) to establish a qualifying body.

1174 Section 153(5) also allows the Secretary of State to issue directions to those using the power on his behalf about how exactly to conduct their exercise of these functions.

1175 The section also adds the new subsection (1A) to section 154. This allows the Secretary of State to make an arrangement with any third party other than a Special Health Authority for the powers under new section 149(1A) to be exercised on their behalf.

Professional Regulation

Section 168: Regulation of health care and associated professions

1176 This section amends sections 60 and 62 of and Schedule 3 to the Health Act 1999 and enables further changes to be made through secondary legislation to the professional regulation system.

1177 Subsection (2)(a) and (b) of this section amends section 60 by inserting new subsection (1)(bza) and (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. Subsection (2)(c) substitutes a new subsection (2) into section 60 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 subsection (2ZB) of section 60 to make clear the new power to take professions out of regulation includes the currently un-enacted provisions concerning social care workers in England.

1178 Subsection (3) amends section 62 of the Health Act 1999 to require the consent of the Welsh Ministers to any provision in an Order in Council made by virtue of section 60(2ZZA) that is within the legislative competence of Senedd Cymru, and is not merely incidental to, or consequential on provision that would be outside of that competence.

1179 Subsection (4)(a) and (b) amends Schedule 3 to the Health Act 1999 (by inserting a new paragraph 1C and removing sub-paragraphs (1) and (1A) of paragraph 7) to permit the abolition of an individual health and care professional regulatory body, where the professions it regulates will continue to be regulated by another regulatory body or where the professions have been deregulated. This power includes the regulation of social care workers in England for which the power to regulate in legislation is not currently enacted.

1180 Previous restrictions on the power for health and care regulatory bodies to delegate their functions in Schedule 3, paragraph 8, through legislation are amended by subsection (4)(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 provisions 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

Section 169: Medical Examiners

1181 This section makes a number of amendments to Part 1, Chapter 2 of the Coroners and Justice Act 2009 (Notification, certification, and registration of deaths) and an amendment to both the Births and Deaths Registration Act 1953 and the 2012 Act.

1182 Subsection (1) inserts sections 18A (Medical examiners: England) and 18B (Medical Examiners: Wales) into the Coroners and Justice Act 2009.

1183 Section 18A contains four subsections, 18A(1) to 18A(4).

1184 Section 18A(1) introduces a power for English NHS bodies to appoint medical examiners.

1185 Section 18A(2) introduces 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.

1186 Section 18A(3) introduces a power for the Secretary of State 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.

1187 Section 18A(4) defines English NHS body for the purposes of section 18A as:

a. NHS England;

b. an integrated care board;

c. a NHS Trust;

d. a Special Health Authority; or

e. a NHS Foundation Trust.

1188 Section 18B contains three subsections, 18B(1) to 18B(3).

1189 Section 18B(1) introduces a power for Welsh NHS bodies to appoint medical examiners.

1190 Section 18B(2) introduces a duty on Welsh Ministers to ensure that enough medical examiners are appointed in the healthcare system in Wales, that enough funds and resources are made available to medical examiners to enable them to carry out their functions of scrutiny to identify and deter poor practice, and to ensure that their performance is monitored.

1191 Section 18B(3) defines a Welsh NHS body for the purposes of section 18B as:

a. a Local Health Board;

b. a NHS Trust; or

c. a Special Health Authority.

1192 Subsection (2)(a) amends the heading of section 19 of the Coroners and Justice Act 2009 to "Medical Examiners: supplementary".

1193 Subsection (2)(b) removes subsections 19(1) and (2) of the Coroners and Justice Act 2009, which previously made provision for local authorities in England, and Local Health Boards in Wales, to appoint persons as medical examiners.

1194 Subsection (2)(c) amends section 19(5) of the Coroners and Justice Act 2009 to provide that nothing in sections 18A, 18B or 19 of that Act provides English or Welsh NHS bodies any role in relation to the way in which medical examiners exercise their professional judgment as medical practitioners.

1195 Subsection (3) amends section 20(5) of the Coroners and Justice Act 2009 (Medical certificate cause of death), 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 or Welsh NHS body.

1196 Subsection (4) amends Section 48(1) of the Coroners and Justice Act 2009 (Interpretation: general) to provide that the definition of a medical examiner is a person appointed under Section 18A or 18B.

1197 Subsection (5) amends section 41(1) of the Births and Deaths Registration Act 1953 to provide that the definition of medical examiner in that Act has the same meaning as section 48(1) of the Coroners and Justice Act 2009.

1198 Subsection (6) amends the 2012 Act removing the provision which inserted references to English local authorities initially into the Coroners and Justice Act 2009.

Organ trafficking

Section 170: Commercial dealings in organs for transplantation: extra-territorial offences

1199 This section inserts new section 32A into the Human Tissue Act 2004 and new section 20A into the Human Tissue (Scotland) Act 2006, to extend the prohibition of commercial dealings in human material for transplantation to acts done outside of the UK when the material concerned is a human organ and when the act is committed by a person who is habitually resident in England, Wales or Scotland or is a UK national who is not habitually resident in Northern Ireland.

1200 The section makes it an offence to pay for the supply of an organ, pay for an offer to supply an organ, or seek somebody willing to supply an organ for payment anywhere in the world. It would also make it an offence to supply, or offer to supply, an organ for payment anywhere in the world. This includes initiating or negotiating any arrangement involving the giving of a reward for the supply of, or for an offer to supply, an organ, and taking part in the management of a body that does so.

Human Fertilisation and Embryology

Section 171: Storage of gametes and embryos

1201 This section introduces a Schedule relating to the storage of gametes and embryos. New section 171 introduces Schedule 17. Part 1 of Schedule 17 amends section 14, section 17, and section 47 of, and Schedule 3 to, the Human Fertilisation and Embryology Act 1990 (the "1990 Act").

Schedule 17: Storage of gametes and embryos

1202 Paragraph 2(3) of Schedule 17 substitutes section 14, subsections (3) to (5), of the 1990 Act to clarify the new maximum statutory storage period for gametes and embryos.

1203 New subsection (3)(a) and 3(b) of section 14 of the 1990 Act state that the maximum statutory storage period is 55 years for gametes and embryos to be used in fertility treatment.

1204 New subsection (3)(c) sets out that embryos that are to be used in research or for training purposes but not for treatment purposes can only be kept in storage for a maximum of 10 years. The 10-year period will start on the day that the embryo was first placed into storage for research or training purposes, or on the day that consent was provided specifically for storage for research or training purposes, if the materials have been in storage for alternative purposes (such as treatment) previously.

1205 New subsection (3)(d) states that the maximum storage limit of 10 years will also apply to human admixed embryos. Admixed embryos are embryos which contain both human and animal DNA. The creation of admixed embryos has been allowed since the 2008 Act; however, their use is restricted to research only. Admixed embryos are only allowed to be kept for up to 14 days from the day on which the process of creating the human admixed embryo began or until the appearance of the primitive streak, whichever comes first. This is consistent with the time limits for keeping human embryos *in vitro* for research purposes. The

research use of admixed embryos to date has been limited and it was determined that there is no reason to change the maximum storage limit for admixed embryos.

1206 The substitution made by paragraph 2(3) of Schedule 17 to section 14(3) to (5) of the 1990 Act also removes the regulation making power previously set out in section 14(5) of the 1990 Act, so that the Secretary of State is no longer able to change gamete and embryo storage limits by way of regulations. This means that the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (the "2009 Regulations") and the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 (the "2020 Regulations"), no longer apply following commencement of these provisions on 1 July 2022. Consent provided for the storage of material under these two sets of Regulations before they are revoked will remain effective. The 2009 Regulations allowed those who were classed as "prematurely infertile" to extend the storage limit for ten-year periods up to a maximum of 55 years. The 2020 Regulations allowed an additional two-year storage on top of the maximum base limit of ten years for those with material in storage on 1 July 2020. This was introduced as a response to the COVID-19 pandemic, which resulted in the closure to fertility clinics and ongoing delays to fertility treatments.

1207 The new subsection (5) inserted into section 14 of the 1990 Act sets out the definitions of "treatment purposes", "training purpose", and "research purpose" for the purposes of that section.

Disposal of material

1208 Paragraph 5 inserts a new paragraph (ca) following section 14(1)(c) of the 1990 Act to make clear that storage facilities must dispose of gametes and embryos when storage is no longer lawful. This insertion also modernises the language of the 1990 Act. A similar update was made to section 17(1)(c) by Paragraph 6.

Consent to storage

1209 Paragraph 7(1), (2), and (3) of Schedule 17 amends Schedule 3, paragraph 1 of the 1990 Act so that where consent to 10 year's storage is renewed, that renewal must be in writing and must be signed by the person giving consent, unless there are specific exemptions in place.

Renewal of consent to storage of gametes

1210 Paragraph 7(4) inserts new paragraphs 11A to 11D into Schedule 3 to the 1990 Act. The new paragraphs 11A and 11B specify the requirement for 10-year review periods and consent renewals as a condition to continue the storage of gametes up to the maximum of 55 years. These new requirements will need to be complied with as a condition of any storage licence granted under the 1990 Act by facilities storing gametes.

1211 Paragraph 11A applies the renewal requirements to people who are storing their gametes for the purposes of their treatment alone or with a partner, including for the purposes of surrogacy arrangements. The facility storing the gametes must attempt to contact the person storing their gametes 1 year in advance of expiry of any 10-year storage period and request that consent for ongoing storage is renewed. If the person whose gametes are in storage does not renew their consent, then their consent may be taken as withdrawn after certain requirements have been met. The facility must then attempt to contact the person storing their gametes on or around the date of expiry to tell them that their storage period has come to an end. If the gamete provider does not provide renewed consent, the facility must dispose of the gametes 6 months following the expiry of consent to store. This is effectively a "cooling off" period to allow for disposal.

1212 Paragraph 11A(9) provides for a 10-year grace period for storage, if a person storing their gametes dies. This provision will only apply if consent to posthumous storage and use is in place prior to the individual's death, in which the person storing their gametes specifies that their partner can use their gametes in treatment posthumously. The surviving partner will need to provide a death certificate to validate the storage extension and enable use of the gametes in their treatment. This will be a one-off extension of 10-years calculated from the date of death of the gamete provider. If at the end of the 10-year grace period the deceased person's gametes are still in storage, the storage facility must dispose of them.

1213 Paragraph 11A(10) to (12) provides for a 10-year grace period, if a person storing their gametes becomes incapacitated. This provision will only apply if consent is in place prior to the incapacitation in which the person storing their gametes specifies that their partner can use their gametes in treatment in the event the person loses capacity. For the 10-year period to apply, a registered medical practitioner must certify that the person does not have capacity and that they are unlikely to regain it. The 10-year grace period would apply from the date of the medical professional's certification. If the person storing their gametes regains capacity within the 10-year grace period, then they will be able to renew their consent and continue storage as before. If at the end of the 10-year grace period the incapacitated person's gametes are still in storage, and they have not regained capacity or not informed the storage facility that they had, then the storage facility must dispose of the gametes.

1214 The renewal of consent requirements set out in paragraph 11A do not apply to donated gametes stored for the treatment of others.

1215 Paragraph 11B sets out the definitions for terms used in paragraph 11A including of a "consent period", the "relevant day", the "renewal period", and what is meant by persons "lacking capacity" respectively. Paragraph 11B(8) allows provisions relating to capacity to be interpreted in line with the Scottish definition of incapacity, where persons are undergoing treatment in Scotland.

Renewal of consent to storage of embryos

1216 Paragraph 11C (Renewal of consent to storage of embryos) applies to people who are storing their embryos, created in vitro, for the purposes of their treatment or that of a partner, including for the purposes of surrogacy arrangements. This paragraph applies in the same way as paragraph 11A, subject to the exception that both gamete providers must provide consent to storage, and the facility storing the material must contact both persons whose gametes have been used to produce the embryo, in order to renew consent, unless one set of gametes is provided by a third-party donor. If either of the gamete providers fail to renew their consent before the 6 months after the consent expires, subject to certain requirements, consent for storage will be taken as withdrawn and the facility must dispose of the embryo(s) following another 6 months cooling off period.

1217 The renewal of consent requirements set out in paragraph 11C do not apply to donated embryos stored for the treatment of others.

1218 Paragraph 11C(9) provides for a 10-year grace period, if a person storing their embryos dies, to the same effect as paragraph 11A(9).

1219 Paragraph 11C(10) to 11C(12) provides for a 10-year grace period, if a person storing their embryos becomes incapacitated, to the same effect as paragraph 11A(10) to 11A(12).

1220 Paragraph 11D contains relevant definitions and interpretations rules, similar to paragraph 11B.

Part 2 of Schedule 17

1221 Part 2 of new Schedule 17 contains paragraphs 8 to 18 of which set out the transitional provisions. Paragraph 8 sets out the definitions for terms used in this Part of this Schedule, including “the commencement day” and the “transitional period”.

Application of Part 1 to material already in storage

1222 Paragraphs 9 and 10 stipulate that the new provisions will apply to pre-commencement licences if the gametes or embryos are still stored at commencement. The new requirement for 10-year renewal periods will apply to gametes and embryos that were stored pre-commencement.

1223 As set out in Paragraph 9(2) the new provision will not however apply to embryos already in storage on the commencement day (1 July 2022), which are stored for the purposes of research or training only, and not for treatment purposes. These embryos will continue to be stored lawfully until the end of their statutory storage period as set out in the 1990 Act.

Date of first storage

1224 Paragraph 11 applies to rare cases, where the gametes or embryos are stored under a pre-commencement licence and where, at the end of the transitional period, the storage facility has taken all “reasonable steps” to establish the date on which the material first went into storage but was unable to establish that exact date. In these instances, the storage facility can provide the gamete or embryo provider(s) with a new date from which the statutory storage period will continue to be calculated from.

Storage periods specified in pre-commencement storage licences

1225 Paragraph 12 provides that for any gametes and embryos in storage under pre-commencement licence under the 1990 Act, the period of 55 years began on the day on which the gametes or embryos were first entered into storage. For example, if a person stored their gametes for the first time on the 5 July 2014 then their maximum statutory storage period of 55 years would be calculated from that date. They would then be able to lawfully store their gametes, containing the 10-year renewal periods, until the 4 July 2069. These provisions do not apply to embryos in storage for the purposes of research or training only.

Storage after expiry of pre-commencement consent

1226 Paragraph 13 sets out that if gametes or embryos are in storage on pre-commencement licences, under the 1990 Act, and the consent expires during the transitional period, then they will not be automatically treated as being stored unlawfully. This will allow clinics time to implement the new system and contact patients regarding future consent during the transitional period without risk of unlawful storage.

Storage with no effective consent prior to commencement

1227 Paragraph 14 applies to gametes and embryos in storage under pre-commencement licences, where immediately before the commencement day (1 July 2022), there is no effective consent in place. In these cases, the storage facility must request the person whose gametes or embryos are in storage to provide consent. The request must be given in writing by the 1 July 2023, a year from the commencement date. The gamete provider will have the remainder of the transition period, until the 1 July 2024, to provide their consent for ongoing storage. During this period, the gametes or embryos in storage will not be treated as being stored unlawfully.

Time for first renewal of consent

1228 Paragraphs 15 and 16 apply to gametes and embryos in storage either under the 2009 Regulations or the 2020 Regulations. These paragraphs specify that the 10-year consent renewal date will be 10-years following the beginning of the relevant statutory storage period. The consent renewal date is calculated from whenever the old statutory storage period was due to expire. For example, for gametes stored under the 2009 Regulations, a medical professional's opinion would have been required every 10-years for the gametes to continue to be stored lawfully. Therefore, a new 10-year consent period would start following the date of expiry of the most recent 10-year period, as certified by a medical professional. For gametes or embryos stored under the 2020 Regulations, consent would have to be renewed following expiry of consent given under the 2020 Regulations.

Renewals falling due in the transitional period

1229 Paragraphs 17 and 18 apply to gametes or embryos stored under Schedule 3 of the 1990 Act for which the first 10-year renewal period ends within the transitional period. For these cases, the facility storing the gametes or embryos must contact the person storing their gametes or embryos before 1 July 2023 and consent must be secured in writing before 1 July 2024. If consent is not renewed by this time, then the gametes or embryos must be removed from storage and disposed of.

Food and Drink

Section 172: Advertising of less healthy food and drink

This section inserts Schedule 18, which amends the Communications Act 2003 to restrict the advertising of certain food and drink products. This schedule is divided into three main 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
- Paragraphs 4 to 6 then make consequential amendments needed to the Communications Act 2003

Schedule 18: Advertising of less healthy food and drink

Part 1: Programme services: Watershed

Paragraph 1: Television programme services

1230 Paragraph 1 of Schedule 18 inserts new section 321A into the Communications Act 2003.

1231 Subsection (1) of the new section 321A requires OFCOM to set standards to prohibit the advertising of identifiable less healthy food and drink products on television programmes between 5.30 a.m. and 9 p.m., and subsection (2) confirms this must take effect from the beginning of 1 January 2023. Subsection (6) gives the Secretary of State the power to amend the date in subsection (2) to a later date.

1232 Subsection (3) sets out that the prohibition must not apply to advertisements by food or drink small and medium sized enterprises ("SMEs"); and any advertisements exempted in any regulations made by the Secretary of State.

1233 Subsection (4)(a) confirms that "advertisements" include those under sponsorship agreement and, for the purpose of these restrictions, sponsorship credits around television programmes. Products are "identifiable" if a person could reasonably be expected to identify the advertisements as being for that product (subsection (4)(b)). Products are determined to be "less healthy" via a two stage approach (subsection (4)(c)). 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[17]" will need to be applied. Subsection (7) confirms that the Secretary of State may amend the definition of "relevant guidance" through regulations. Subsection (4)(e) 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.

1234 Subsection (8) states that before the Secretary of State can make any regulations for additional exemptions under subsection (3)(b) or amend the relevant guidance under subsection (7) they are under a duty to consult. Subsection (9) confirms that any changes made to the definition of "relevant guidance" in regulations must be subject to the draft affirmative procedure.

Paragraph 2: On-demand programme services

1235 Paragraph 2 inserts a new section 368FA in the Communications Act 2003.

1236 Subsection (1) of new section 368FA, from the beginning of 1 January 2023, introduces a restriction on the advertising of less healthy food and drink on on-demand programme services between 5.30 a.m. and 9 p.m. Subsection (6) gives the Secretary of State the power to amend the date in subsection (1) to a later date.

1237 Subsection (2) states that the prohibition will not apply to advertisements by food or drink SMEs.

1238 Subsection (3) provides that further exemptions to the prohibition may be made by regulations by the Secretary of State.

1239 Subsection (4) confirms that "advertisements" include those under sponsorship agreement and, for the purpose of these restrictions, sponsorship announcements. 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[18]", will need to be applied. Subsection (7) states that the Secretary of State may amend the definition of "relevant guidance" through regulations. Subsection (4)(e) 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.

1240 Subsection (8) states that before the Secretary of State can make any regulations for additional exemptions under subsection (3) or amend the meaning of "relevant guidance" under subsection (7), they are under a duty to consult. Subsection (8) confirms that any changes made to the definition of "relevant guidance" in regulations must be subject to the draft affirmative procedure.

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[17] "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.

[18] "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.

1241 Paragraph 3 inserts Part 4C Online advertising of less healthy food and drink into the Communications Act 2003, after Part 4B. Part 4C comprises Sections 368Z14 through to 368Z21.

368Z14 Prohibition of paid-for advertising of less healthy food and drink

1242 Subsection (1) prohibits paid-for advertising of identifiable less healthy food and drink online from 1 January 2023.

1243 Subsection (2) confirms that the prohibition does not apply to advertisements by food or drink SMEs. Subsection (3) confirms that the prohibition does not apply to business-to-business advertisements. 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, and advertisements that are not intended to be accessed principally by a UK audience.

1244 Subsection (4) provides that further exemptions to the prohibition may be made by regulations 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.

1245 Subsection (5) 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 in the UK 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[19]" will need to be applied. Subsection (8) confirms that the Secretary of State may amend the definition of "relevant guidance". 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. Likewise, subsection (5) states that regulated radio services will be given meaning by regulations. Subsection (7) gives the Secretary of State the power to amend the date in subsection (1) to a later date and to make corresponding amendments to subsections (11) and (12).

1246 Subsection (9) confirms that before the Secretary of State can make any regulations for additional exemptions under subsection (4) or amend the definition of relevant guidance under subsection (8) they are under a duty to consult. Subsection (10) confirms that changes to made to the definition of relevant guidance through regulations made under subsection (8) must be subject to the draft affirmative procedure.

1247 Subsection (11) confirms that from 1 August 2021 any paid online advertising of less healthy food or drink to be placed online on or after 1 January 2023 amounts to a breach of the prohibition. Subsection (12) confirms that subsection (11) does not apply if arrangements are put in place and reasonable action is taken to remove the advert before 1 January 2023.

368Z15 Enforcement

1248 Subsection (1) details that when the appropriate regulatory authority considers a person is contravening or has contravened the prohibition of paid-for advertising on the internet (section 368Z14), they may give the person an enforcement notification and/or impose

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[19] "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.

a financial penalty on them in accordance with the financial penalties detailed in section 368Z16.

1249 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 or has occurred and that the appropriate regulatory authority has allowed the person considered in breach an opportunity to make representations.

1250 Subsection (3) confirms that enforcement notifications should specify how a person has breached the prohibition, impose requirements on the person to take steps to remedy the breach, provide a reasonable amount of time for a person to remedy and set out the reasons for the appropriate regulatory authority's decision to issue the enforcement notification.

1251 Subsection (4) confirms that remedial actions dictated by the appropriate regulatory authority may include instructing or requesting that specified persons remove advertisements from the internet and/or arranging for advertisements to be modified in specific ways.

1252 Subsection (5) states that a person in receipt of an enforcement notification must comply with it. Subsection (6) outlines that the duty under subsection (5) 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 as detailed in section 368Z16.

368Z16 Financial penalties

1253 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.

1254 Subsection (3) confirms that a person's "relevant business" is any business carried on by the person which involves or is 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 person has been carrying on that business for less than a year the relevant period is the time during which the business has been carried on, 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.

1255 Subsection (4) confirms that to determine the applicable financial penalty under subsection (1) the appropriate regulatory authority must have regard to statements published by OFCOM under section 392 of the Communications Act 2003 (the guidelines to be followed in determining the amount of penalties).

1256 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

1257 Subsection (1) allows the appropriate regulatory authority to give a person a notice demanding information, for the purpose of carrying out their functions under this new Part 4C. 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.

1258 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

1259 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

1260 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.

1261 Subsection (2) confirms that if OFCOM do not designate, that they (OFCOM) will be the appropriate regulatory authority. 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.

1262 Subsections (5) and (6) outline 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

1263 Subsection (1) gives the Secretary of State the power to amend the new Part 4C 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) defines "placing" as including leaving in place and "placed" as including continuing to be placed.

1264 Subsection (3) 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.

1265 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 subject to the draft affirmative procedure.

368Z21 Interpretation

1266 This Part outlines that the "appropriate regulatory authority" is to be construed in accordance with section 368Z19; and that "less healthy", in relation to a food or drink product, has the meaning given by section 368Z14(5)(e). 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 the "relevant guidance", the "Nutrient Profiling Technical Guidance[20]", will need to be applied.

Part 3: Consequential Amendments

1267 These paragraphs make amendments to the Communications Act 2003 to ensure that the new parts detailed in this Act are in line with the rest of the 2003 Act.

1268 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.

Section 173: Hospital Food Standards

1269 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.

1270 This section 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.

[20] "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.

1271 Paragraph (a) amends subsection (3) of section 20 of the Health and Social Care Act 2008 to introduce a new paragraph (da) which gives the Secretary of State a power to impose requirements in relation to food or drink provided or made available to any person on hospital premises in England that are used in connection with carrying on a regulated activity.

1272 Paragraph (b) inserts a new subsection (4A) into 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, and may require that specified descriptions of food or drink are not to be provided or made available .

1273 Paragraph (c) sets out that the definition of hospital for the purposes of this section is defined in section 275 of the NHS 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.

1274 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.

1275 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 (3)(da) of section 20 will be subject to those requirements.

Section 174: Food information for consumers: power to amend retained EU law

1276 This section introduces new section 16(3A) and (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.

1277 Subsection (2) of the section 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) will be subject to the affirmative procedure.

Fluoridation of Water Supplies

Section 175: Fluoridation of water supplies

1278 This section 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 on the Secretary of State.

1279 Subsection (2) amends section 87 of the Water Industry Act 1991. It inserts a new enabling power (section 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).

1280 Subsection (2) also amends section 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.

1281 Subsections (3) and (4) make the necessary amendments to remove the local authorities' power to initiate, vary or terminate schemes in England, with subsections (6) and (8) making amendments consequential upon those changes.

1282 Subsection (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).

1283 Subsections (7) and (9) deal with the regulation making powers under the amended provisions, subsection (7) providing that regulations under the new section 87(6A) will be subject to the affirmative resolution procedure, and subsection (9) providing that the first exercise of the power to make regulations under section 89 (as amended) will be subject to the affirmative resolution procedure.

Section 176: Fluoridation of water supplies: transitional provision

1284 This section 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. This section 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.

Section 177: review into disputes relating to treatment of critically ill children

1285 This section requires the Secretary of State to commission a review of the causes of disputes relating to the care of critically ill children between the providers of care and persons with parental responsibility, how these disagreements can be avoided and how we can sensitively handle their resolution. This will provide evidence-based recommendations to support the creation of healthcare environments that foster good, collaborative relationships between parents and healthcare staff.

1286 The Secretary of State must publish and lay before Parliament a report on the outcome of the review within one year.

Section 178: Early medical termination of pregnancy

1287 Section 178 amends section 1 of the Abortion Act 1967 to make provision for early medical termination of pregnancy to add to the places where treatment for the termination of pregnancy may be provided.

1288 Section 178 inserts new subsections (3B) to (3C) into section 1 of the Abortion Act 1967. Subsection (3B) sets out the circumstances in which subsections (3C) and (3D) apply. The treatment for the termination of pregnancy must be the prescription and administration of medicine, and the registered medical practitioner "RMP" terminating the pregnancy must be of the opinion, formed in good faith, that the pregnancy will not exceed ten weeks at the time when the medicine is administered. If the medicines known as Mifepristone and Misoprostol are prescribed, the pregnancy should not exceed ten weeks when the Mifepristone is administered in accordance with the instructions of the RMP.

1289 In these circumstances, new subsection (3C) provides that an RMP whose usual place of residence is in England or Wales may prescribe the medicine or medicines from their home.

1290 New subsection (3D) provides that a pregnant woman whose usual place of residence is in England or Wales, having had a consultation with an RMP, registered nurse or registered midwife about the termination of the pregnancy, may self-administer the medicine or medicines at home.

Child Safeguarding: Information Sharing

Section 179: Child Safeguarding: Information Sharing

1291 This section requires the Secretary of State to publish and lay before Parliament, within one year of commencement of the section, a report describing the government's policy in relation to information-sharing by or with public authorities in the exercise of children's health and social care functions in England, for purposes relating to children's health or social care or the safeguarding or promotion of the welfare of children. The section will commence three months after Royal Assent. Subsections (3) and (4) set out certain matters which must be covered in the report.

Section 180: Licensing of cosmetic procedures

1292 The current legal framework relating to non-surgical cosmetic procedures is found in various existing legislation. The Local Government (Miscellaneous Provisions) Act 1982 allows local authorities to make provision for the registration of certain cosmetic treatments, including cosmetic piercing, electrolysis, tattooing, semi-permanent make up and acupuncture. However, registration is a very simple process, there is no requirement for the provision of proof of qualifications, and local authorities have few powers to refuse registration.

1293 Some local authorities have made byelaws to regulate non-surgical cosmetic procedures but the content of these is restricted, for example to the cleanliness of premises. In addition, a small number of local authorities in England have introduced local licensing schemes. These include Essex (under the Essex Act 1987), Nottingham (under the Nottinghamshire County Council Act 1985) and London (under the London Local Authorities Act 1991).

1294 The subsection (3)(b) therefore grants the power to repeal local Acts such as these in order to ensure that the licensing scheme is applied uniformly across England so that the same national minimum standards of safety and training qualifications are upheld.

Disability and autism training

Section 181: Mandatory training on learning disability and autism

1295 This section amends the Health and Social Care Act 2008 (the "HSCA 2008)").

1296 Subsection (2) inserts a new subsection (5ZA) into section 20 (regulation of regulated activities) of the HSCA 2008. New subsection (5ZA) places a duty on the Secretary of State to make regulations to require service providers to ensure that persons by working for them for the purpose of regulated activities receive training specifically on learning disability and autism appropriate to the person's role. This introduces a specific requirement to provide learning disability and autism training within the existing CQC regulated framework.

1297 Subsection (3) inserts a new subsection (5D) into section 20 of the HSCA 2008 which defines the terms "learning disability" and "service provider" both of which appear in new subsection (5ZA.).

1298 Subsection (4) inserts a new section 21A (Learning disability and autism training: Code of Practice) into Chapter 2 of the HSCA 2008. The new section imposes a duty on the Secretary of State to issue a Code of Practice (CoP) about compliance with requirements set out in regulations relating to training on learning disability and autism.

1299 Section Subsection (2) of new section 21A sets what the CoP must include.

1300 Section Subsection (3) of new section 21A gives the CoP some flexibility to make different provisions for different cases or circumstances.

1301 Section Subsection (4) of new section 21A imposes a duty on the Secretary of State to review the CoP at least every five years and to lay before Parliament a report with the findings of that review.

1302 Subsection (5) makes several amendments to section 22 (consultation in relation to Code of Practice under section 21) of the HSCA 2008.

1303 Subsection (5) (a) changes the heading of section 22 to reflect the scope of section 22. It now covers the CoP in new section 21A as well as the pre-existing CoP in section 21 on health care associated infections.

1304 Subsections (5) (b) and (5) (c) add references to the new section 21A into subsections (1) and (2) of section 22. The references function to ensure that the duties for the Secretary of State to prepare a draft and consult on COP under section 21are also applied to the new CoP for learning disability and autism training.

1305 Subsection (5)(d) makes subsection (3) of section 22 apply only to a draft or revised CoP made under section 21 (health care associated infections). Subsection (3) relates to when a CoP under the HSCA 2008 comes into force. By doing so it means that subsection (3) does not apply to the CoP made under new section 21A.

1306 Subsection (5)(e) inserts new subsections (5A) to (5D) into section 22 of the HSCA 2008. Subsection (5A) places a duty on the Secretary of State to lay a copy of the draft CoP before Parliament following a consultation. Subsections (5B) sets out that if either House of Parliament resolves not to approve it within a 40-day period following laying, the Secretary of State cannot issue the CoP. Subsections (5C) and (5D) provide clarification on how the 40-day period is calculated.

1307 Subsection (6) adds references to new section 21A into section 25 of the HSCA 2008. This ensures that the CoP may be taken into account in the making of certain decisions or in certain proceedings under the HSCA 2008 and makes the CoP admissible as evidence in other criminal or civil proceedings. Subsection (7) sets out that until the first regulations made using powers in new subsection (5ZA) come into force, the HSCA 2008 and the 2014 Regulations, should be read as if regulation 18 of the 2014 regulations already contain the requirements set out in subsection (5ZA) for learning disability and autism training. In practice this means that from commencement of these provisions in the Health and Care Act, the 2014 Regulations and HSCA 2008 are to be read as including a requirement for all health and social care providers who carry out regulated activities to ensure that their staff receive specific training on learning disabilities and autism appropriate to their role.

Part 7: General

Section 182: Power to make consequential provision

1308 This section provides a power which allows the Secretary of State, by regulations, to make provision that is consequential on this Act.

1309 In particular, the power may be used to amend, repeal, revoke or otherwise modify any provision within this Act or any provision made by or under primary legislation passed either before this Act is passed or later in the same Parliamentary session (subsection (2)).

1310 Where regulations modify primary legislation, the affirmative parliamentary procedure must be used. Otherwise, the regulations can be made under the negative parliamentary procedure. This provision may be used to amend primary legislation passed in any part of the United Kingdom (subsection (3)).

Section 183: Regulations

1311 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.

1312 Subsection (2) enables regulations made under the sections listed to make different provision for England, Wales, Scotland or Northern Ireland.

1313 Subsection (3) clarifies that regulations under this Act are to be made by statutory instrument.

1314 Subsection (4) specifies that regulations made under the following powers in the Act must be subject to the affirmative parliamentary procedure:

- Section 20 (4) regarding integrated care board responsibility

- Section 92 regarding information about payments etc to persons in the health care sector
- Section 103 and 104 regarding the power to transfer functions between Arm's Length Bodies Section 123 regarding exceptions to HSSIB's prohibition on disclosure
- Section 180 regarding licensing of cosmetic regulation
- Section 182 if any regulations are laid using this power to amend Primary legislation.

1315 Subsection (6) provides that this section does not apply to commencement regulations.

Section 184: Financial provision

1316 This section deals with the further financial provision necessary as a result of the Act.

Section 185: Extent

1317 This section sets out the territorial extent of the Act, that is the jurisdictions within which the Act forms part of the law.

1318 Subsection (1) provides that the Act extends to England and Wales only with the exception of sections specified in subsections (2), (3)) and (4). In addition, subsection (5) provides that an amendment, repeal or revocation made by this Act has the same extent as the provision it is amending, repealing or revoking.

1319 Subsection (2) sets out that the following sections of the Act extend to England and Wales, Scotland and Northern Ireland:

- Part 1: paragraph 1(3) or (4) of Schedule 1 (renaming of NHS Commissioning Board);
- Part 2: Sections 92 to 94 (information about payments etc. to persons in the health care sector);
- Part 3 (Secretary of State's powers to transfer or delegate functions);Part 4: section 125 (restriction of statutory powers requiring disclosure;
- Part 6: section 171 and Part 2 of Schedule 17 (storage of gametes and embryos);
- Part 7.)

1320 Subsection (3) sets out that the following sections apply to Scotland only:

- Sections 140 to 143 (offences relating to virginity testing);
- Sections 152 to 155 (offences relating to hymenoplasty).

1321 Subsection (4) sets out that the following sections apply to Northern Ireland only:

- Sections 144 to 147 (offences relating to virginity testing);
- Sections 156 to 159 (offences relating to hymenoplasty).

Section 186: Commencement

1322 This section provides that Part 7 of the Act 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).

1323 Subsection (2) provides that section 161(2), which relates to pharmaceutical services, comes into force when Welsh Ministers appoint so by regulations.

1324 Section 171 and Schedule 17 (storage of gametes and embryos) to come into force on 1 July 2022. While Section 172 and Schedule 18 (advertising of less healthy food and drink) come into force 28 June 2022. Section 179 will come into force on 28 July 2022.

1325 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 Act. The Welsh Ministers also have a power to make regulations to make transitional or saving provision in respect of section 161(2).

Section 187: Short title

1326 This section states the Act's short title as "The Health and Care Act 2022".

Related documents

1327 The following documents are relevant to the Act and can be read at the stated locations:

- *Integration and Innovation Working together to Improve Health and Social Care for All White Paper*, https://www.gov.uk/government/publications/working-together-to-improve-health-and-social-care-for-all
- *NHS Recommendations to Government and Parliament for an NHS Bill*, https://www.england.nhs.uk/wp-content/uploads/2019/09/BM1917-NHS-recommendations-Government-Parliament-for-an-NHS-Act.pdf
- *NHS Long Term Plan*, https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf
- *Integrating Care : Next Steps to Building Strong and Effective Integrated Care Systems across England*, https://www.england.nhs.uk/publication/integrating-care-next-steps-to-building-strong-and-effective-integrated-care-systems-across-england/
- *Regulating healthcare professionals, protecting the public*, https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public
- *Reducing Bureaucracy in the Health and Social Care System*, https://www.gov.uk/government/consultations/reducing-bureaucracy-in-the-health-and-social-care-system-call-for-evidence/reducing-bureaucracy-in-the-health-and-social-care-system-background-and-questions
- A review of the Fit and Proper Person's Test, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/787955/kark-review-on-the-fit-and-proper-persons-test.pdf
- *Promoting Professionalism, reforming regulation*, https://www.gov.uk/government/consultations/promoting-professionalism-reforming-regulation
- *Promoting Professionalism, reforming regulation: Government Response to Consultation*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf
- *Regulation of Health and Social Care Professionals*, https://s3-eu-west-2.amazonaws.com/lawcom-prod-storage-11jsxou24uy7q/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf
- *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*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/445640/Learning_not_blaming_acc.pdf

- *Independent Review of NHS Hospital Food*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/929234/independent-review-of-nhs-hospital-food-report.pdf

- *Introducing further advertising restrictions on TV and online for products high in fat, sugar and salt (HFSS)*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/807378/hfss-advertising-consultation-10-april-2019.pdf

- *Introducing a total online advertising restriction for products high in fat, sugar and salt (HFSS)*, https://www.gov.uk/government/consultations/total-restriction-of-online-advertising-for-products-high-in-fat-sugar-and-salt-hfss/introducing-a-total-online-advertising-restriction-for-products-high-in-fat-sugar-and-salt-hfss

- T*ackling obesity: empowering adults and children to live healthier lives*, https://www.gov.uk/government/publications/tackling-obesity-government-strategy/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*, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/216094/dh_123492.pdf

- *Data saves lives: reshaping health and social care with data (draft):* https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data-draft/data-saves-lives-reshaping-health-and-social-care-with-data-draft

- *Gamete (egg, sperm) and embryo storage limits: response to consultation:* https://www.gov.uk/government/consultations/egg-sperm-and-embryo-storage-limits/outcome/gamete-egg-sperm-and-embryo-storage-limits-response-to-consultation

- *Regulatory triage assessment: for increasing gamete and embryo storage limits to a maximum of 55 years for all:* https://www.gov.uk/government/consultations/egg-sperm-and-embryo-storage-limits/outcome/regulatory-triage-assessment-for-increasing-gamete-and-embryo-storage-limits-to-a-maximum-of-55-years-for-all

- *First Do No Harm:* The report of the independent medicines and medical devices safety review: https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

- *Independent Medicines and Medical Devices Safety Review: Government Response:* https://www.gov.uk/government/publications/independent-medicines-and-medical-devices-safety-review-government-response

Annex A – Territorial extent and application in the United Kingdom

Subject matter and legislative competence of devolved legislatures

1328 In the opinion of the UK Government, the subject matter of the Act is within the devolved competence of the Welsh, Scottish and Northern Irish legislatures because it relates to health. Health policy and funding are controlled by the respective Devolved Administrations.

1329 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.

1330 The exceptions are:

- Section 168: 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 of healthcare workers is an entirely reserved matter under the Wales Act 2006. Not excepted are orders in council made under section 60 of the Health Act 1999 to bring into regulation groups of workers who are concerned with physical or mental health of individuals, but who are not generally regarded as a profession.

- Section 125: Restriction of statutory powers requiring disclosure. This section 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.

- Sections 113 and 114. These could have some practical effect in Wales as a result of a request for assistance or agreement in relation to section 111 or 112, but this would not involve any devolved legislation being affected.

- Section 172 and Schedule 17: Advertising of less healthy food and drink. While food and health are within devolved competence in all three devolution settlements, Internet services and broadcasting matters are reserved in all three 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).

Annex B – Hansard References

1331 The following table sets out the dates and Hansard references for each stage of the Act's passage through Parliament.

Stage	Date	Hansard Reference
House of Commons		
Introduction	6 July 2021	Vol. [698] Col. [784]
Second Reading	14 July 2021	Vol. [699] Col. [425]
Public Bill Committee	7 September 2021	First sitting: Col. [1-34]
		Second sitting: Col. [35-84]
	9 September 2021	Third sitting: Col. [85-112]
		Fourth sitting: Col. [113-168]
	14 September 2021	Fifth sitting: Col. [169-204]
		Sixth sitting: [205-262]
	16 September 2021	Seventh sitting: Col. [263-286]
		Eighth sitting: Col. [287-344]
	21 September 2021	Ninth sitting: Col. [345-380]
		Tenth sitting: Col. [381-428]
	23 September 2021	Eleventh sitting: Col. [429-456]
		Twelfth sitting: Col [457-504]
	19 October 2021	Thirteenth sitting: Col. [505-538]
		Fourteenth Sitting: Col. [539-594]
	21 October 2021	Fifteenth sitting: Col. [595-598]
	26 October 2021	Sixteenth sitting: Col. [599-630]
		Seventeenth sitting: Col. [631-692]
	27 October 2021	Eighteenth sitting: Col. [693-734]
		Nineteenth sitting: Col. [735-800]
	28 October 2021	Twentieth sitting: Col. [801-832]
		Twenty First sitting: Col. [833-880]
	2 November 2021	Twenty Second sitting Col. [881-910]
Report and Third Reading	22 November 2021	Vol. [704] Col. [48]
	23 November 2021	Vol. [704] Col. [201]
		Vol. [704] Col. [310]
House of Lords		
Introduction	24 November 2021	Vol. [816]
Second Reading	7 December 2021	Vol. [816] Col. [1779]
Grand Committee	11 January 2022	Vol. [817] Col. [974]
		Vol. [817] Col. [1058]
	13 January 2022	Vol. [817] Col. [1213]

Stage	Date	Hansard Reference
		Vol. [817] Col. [1263]
	18 January 2022	Vol. [817] Col. [1488]
		Vol. [817] Col. [1550]
		Vol. [817] Col. [1622]
	20 January 2022	Vol. [817] Col. [1783]
	24 January 2022	Vol. [818] Col. [26]
		Vol. [818] Col. [94]
	26 January 2022	Vol. [818] Col. [256]
		Vol. [818] Col. [312]
		Vol. [818] Col. [373]
	31 January 2022	Vol. [818] Col. [629]
		Vol. [818] Col. [703]
	4 February 2022	Vol. [818] Col. [1155]
	9 February 2022	Vol. [818] Col. [1651]
		Vol. [818] Col. [1711]
Report	1 March 2022	Vol. [819] Col. [698]
		Vol. [819] Col. [772]
	3 March 2022	Vol. [819] Col. [944]
		Vol. [819] Col. [1009]
	7 March 2022	Vol. [819] Col. [1129]
		Vol. [819] Col. [1215]
	16 March 2022	Vol. [820] Col. [287]
		Vol. [820] Col. [371]
Third Reading	23 March 2022	Vol. [820] Col. [976]
Commons Consideration of Lords Amendments	30 March 2022	Vol. [711] Col. [860]
	25 April 2022	Vol. [712] Col. [522]
Lords Consideration of Commons Amendments	5 April 2022	Vol. [820] Col. [1983]
	26 April 2022	Vol. [821] Col. [219]
Royal Assent	28 April 2022	House of Commons Vol. [712]
		House of Lords Vol. [821] Col. [383]

Annex C – Progress of Bill Table

1332 This Annex shows how each section and Schedule of the Act was numbered during the passage of the Bill through Parliament.

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 1	Clause 1	Clause 1	Clause 1	Clause 1	Clause 1
Section 2	Clause 2	Clause 2	Clause 2	Clause 2	Clause 2
Section 3					Clause 3
Section 4	Clause 3	Clause 3	Clause 3	Clause 3	Clause 4
Section 5			Clause 4	Clause 4	Clause 5
Section 6					Clause 6
Section 7					Clause 7
Section 8	Clause 4	Clause 4	Clause 5	Clause 5	Clause 8
Section 9					Clause 9
Section 10	Clause 5	Clause 5	Clause 6	Clause 6	Clause 10
Section 11					Clause 11
Section 12	Clause 6	Clause 6	Clause 7	Clause 7	Clause 12
Section 13	Clause 7	Clause 7	Clause 8	Clause 8	Clause 13
Section 14	Clause 8	Clause 8	Clause 9	Clause 9	Clause 14
Section 15	Clause 9	Clause 9	Clause 10	Clause 10	Clause 15
Section 16	Clause 10	Clause 10	Clause 11	Clause 11	Clause 16
Section 17	Clause 11	Clause 11	Clause 12	Clause 12	Clause 17
Section 18	Clause 12	Clause 12	Clause 13	Clause 13	Clause 18
Section 19	Clause 13	Clause 13	Clause 14	Clause 14	Clause 19
Section 20	Clause 14	Clause 14	Clause 15	Clause 15	Clause 20
Section 21	Clause 15	Clause 15	Clause 16	Clause 16	Clause 21
Section 22	Clause 16	Clause 16	Clause 17	Clause 17	Clause 22
Section 23	Clause 17	Clause 17	Cause 18	Clause 18	Clause 23
Section 24	Clause 18	Clause 18	Clause 19	Clause 19	Clause 24
Section 25	Clause 19	Clause 19	Clause 20	Clause 20	Clause 25
Section 26	Clause 20	Clause 20	Clause 21	Clause 21	Clause 26
Section 27	Clause 21	Clause 21	Clause 22	Clause 22	Clause 27
Section 28	Clause 22	Clause 22	Clause 23	Clause 23	Clause 28
Section 29	Clause 23	Clause 23	Clause 24	Clause 24	Clause 29
Section 30	Clause 24	Clause 24	Clause 25	Clause 25	Clause 30
Section 31		Clause 25	Clause 26	Clause 26	Clause 31
Section 32		Clause 26	Clause 27	Clause 27	Clause 32

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 33	Clause 26	Clause 27	Clause 28	Clause 28	Clause 33
Section 34	Clause 27	Clause 28	Clause 29	Clause 29	Clause 34
Section 35	Clause 28	Clause 29	Clause 30	Clause 30	Clause 35
Section 36	Clause 29	Clause 30	Clause 31	Clause 31	Clause 36
Section 37	Clause 30	Clause 31	Clause 32	Clause 32	Clause 37
Section 38	Clause 31	Clause 32	Clause 33	Clause 33	Clause 38
Section 39	Clause 32	Clause 33	Clause 34	Clause 34	Clause 39
Section 40					Clause 40
Section 41	Clause 33	Clause 34	Clause 35	Clause 35	Clause 41
Section 42	Clause 34	Clause 35	Clause 36	Clause 36	Clause 42
Section 43	Clause 35	Clause 36	Clause 37	Clause 37	Clause 43
Section 44	Clause 36	Clause 37	Clause 38	Clause 38	Clause 44
Section 45	Clause 37	Clause 38	Clause 39	Clause 39	Clause 45
Section 46	Clause 39	Clause 40	Clause 41	Clause 41	Clause 46
Section 47	Clause 40	Clause 41	Clause 42	Clause 42	Clause 47
Section 48	Clause 41	Clause 42	Clause 43	Clause 43	Clause 48
Section 49	Clause 42	Clause 43	Clause 44	Clause 44	Clause 49
Section 50	Clause 43	Clause 44	Clause 45	Clause 45	Clause 50
Section 51					Clause 51
Section 52	Clause 44	Clause 45	Clause 46	Clause 46	Clause 52
Section 53	Clause 45	Clause 46	Clause 47	Clause 47	Clause 53
Section 54	Clause 46	Clause 47	Clause 48	Caluse 48	Clause 54
Section 55	Clause 47	Clause 48	Clause 49	Clause 49	Clause 55
Section 56	Clause 48	Clause 49	Clause 50	Clause 50	Clause 56
Section 57	Clause 49	Clause 50	Clause 51	Clause 51	Clause 57
Section 58	Clause 50	Clause 51	Clause 52	Clause 52	Clause 58
Section 59	Clause 51	Clause 52	Clause 53	Clause 53	Clause 59
Section 60	Clause 52	Clause 53	Clause 54	Clause 54	Clause 60
Section 61	Clause 53	Clause 54	Clause 55	Clause 55	Clause 61
Section 62	Clause 54	Clause 55	Clause 56	Clause 56	Clause 62
Section 63	Clause 55	Clause 56	Clause 57	Clause 57	Clause 63
Section 64	Clause 56	Clause 57	Clause 58	Clause 58	Clause 64
Section 65	Clause 57	Clause 58	Clause 59	Clause 59	Clause 65
Section 66					Clause 66
Section 67	Clause 58	Clause 59	Clause 60	Clause 60	Clause 67

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 68	Clause 59	Clause 60	Clause 61	Clause 61	Clause 68
Section 69	Clause 60	Clause 61	Clause 62	Clause 62	Clause 69
Section 70	Clause 61	Clause 62	Clause 63	Clause 63	Clause 70
Section 71	Clause 62	Clause 63	Clause 64	Clause 64	Clause 71
Section 72	Clause 63	Clause 64	Clause 65	Clause 65	Clause 72
Section 73	Clause 64	Clause 65	Clause 66	Clause 66	Clause 73
Section 74	Clause 65	Clause 66	Clause 67	Clause 67	Clause 74
Section 75	Clause 66	Clause 67	Clause 68	Clause 68	Clause 75
Section 76	Clause 67	Clause 68	Clause 69	Clause 69	Clause 76
Section 77	Clause 68	Clause 69	Clause 70	Clause 70	Clause 77
Section 78	Clause 69	Clause 70	Clause 71	Clause 71	Clause 78
Section 79					Clause 79
Section 80	Clause 70	Clause 71	Clause 72	Clause 72	Clause 80
Section 81	Clause 71	Clause 72	Clause 73	Clause 73	Clause 81
Section 82	Clause 72	Clause 73	Clause 74	Clause 74	Clause 82
Section 83	Clause 73	Clause 74	Clause 75	Clause 75	Clause 83
Section 84	Clause 74	Clause 75	Clause 76	Clause 76	Clause 84
Section 85	Clause 75	Clause 77	Clause 77	Clause 77	Clause 85
Section 86					Clause 86
Section 87	Clause 76	Clause 78	Clause 78	Clause 78	Clause 87
Section 88	Clause 77	Clause 79	Clause 79	Clause 79	Clause 88
Section 89	Clause 78	Clause 80	Clause 80	Clause 80	Clause 89
Section 90					Clause 90
Section 91				Clause 81	Clause 91
Section 92				Clause 82	Clause 92
Section 93				Clause 83	Clause 93
Section 94	Clause 79	Clause 81	Clause 81	Clause 84	Clause 94
Section 95	Clause 80	Clause 82	Clause 82	Clause 85	Clause 95
Section 96	Clause 81	Clause 83	Clause 83	Clause 86	Clause 96
Section 97	Clause 82	Clause 84	Clause 84	Clause 87	Clause 97
Section 98	Clause 83	Clause 85	Clause 85	Clause 88	Clause 98
Section 99	Clause 84	Clause 86	Clause 86	Clause 89	Clause 99
Section 100	Clause 85	Clause 87	Clause 87	Clause 90	Clause 100
Section 101	Clause 86	Clause 88	Clause 88	Clause 91	Clause 101
Section 102	Clause 87	Clause 89	Clause 89	Clause 92	Clause 102

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 103	Clause 88	Clause 90	Clause 90	Clause 93	Clause 103
Section 104	Clause 89	Clause 91	Clause 91	Clause 94	Clause 104
Section 105	Clause 90	Clause 92	Clause 92	Clause 95	Clause 105
Section 106	Clause 91	Clause 93	Clause 93	Clause 96	Clause 106
Section 107	Clause 92	Clause 94	Clause 94	Clause 97	Caluse 107
Section 108	Clause 93	Clause 95	Clause 95	Clause 98	Clause 108
Section 109	Clause 94	Clause 96	Clause 96	Clause 99	Clause 109
Section 110	Clause 95	Clause 97	Clause 97	Clause 100	Clause 110
Section 111	Clause 96	Clause 98	Clause 98	Clause 101	Clause 111
Section 112	Clause 98	Clause 99	Clause 99	Clause 102	Clause 112
Section 113	Clause 98	Clause 100	Clause 100	Clause 103	Clause 113
Section 114	Clause 99	Clause 101	Clause 101	Clause 104	Clause 114
Section 115	Clause 100	Clause 102	Clause 102	Clause 105	Clause 115
Section 116	Clause 101	Clause 103	Clause 103	Clause 106	Clause 116
Section 117	Clause 102	Clause 104	Clause 104	Clause 107	Clause117
Section 118	Clause 103	Clause 105	Clause 105	Clause 108	Clause 118
Section 119	Clause 104	Clause 106	Clause 106	Clause 109	Clause 119
Section 120	Clause 105	Clause 107	Clause 107	Clause 110	Clause 120
Section 121	Clause 106	Clause 108	Clause 108	Clause 111	Clause 121
Section 122	Clause 107	Clause 109	Clause 109	Clause 112	Clause 122
Section 123	Clause 108	Clause 110	Clause 110	Clause 113	Clause 123
Section 124	Clause 109	Clause 111	Clause 111	Clause 114	Clause 124
Section 125	Clause 110	Clause 112	Clause 112	Clause 115	Clause 125
Section 126	Clause 111	Clause 113	Clause 113	Clause 116	Clause 126
Section 127	Clause 112	Clause 114	Clause 114	Clause 117	Clause 127
Section 128	Clause 113	Clause 115	Clause 115	Clause 118	Clause 128
Section 129	Clause 114	Clause 116	Clause 116	Clause 119	Clause 129
Section 130	Clause 115	Clause 117	Clause 117	Clause 120	Clause 130
Section 131	Clause 116	Clause 118	Clause 118	Clause 121	Clause 131
Section 132	Clause 117	Clause 119	Clause 119	Clause 122	Clause 132
Section 133	Clause 118	Clause 120	Clause 120	Clause 123	Clause 133
Section 134	Clause 119	Clause 121	Clause 121	Clause 124	Clause 134
Section 135			Clause 122	Clause 125	Clause 135
Section 136			Clause 123	Clause 126	Clause 136
Section 137			Clause 124	Clause 127	Clause 137

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 138			Clause 125	Clause 128	Clause 138
Section 139			Clause 126	Clause 129	Clause 139
Section 140			Clause 127	Clause 130	Clause 140
Section 141			Clause 128	Clause 131	Clause 141
Section 142			Clause 129	Clause 132	Clause 142
Section 143			Clause 130	Clause 133	Clause 143
Section 144			Clause 131	Clause 134	Clause 144
Section 145			Clause 132	Clause 135	Clause 145
Section 146			Clause 133	Clause 136	Clause 146
Section 147				Clause 137	Clause 147
Section148				Clause 138	Clause 148
Section 49				Clause 139	Clause 149
Section 150				Clause 140	Clause 150
Section 151				Clause 141	Clause 151
Section 152				Clause 142	Clause 152
Section 153				Clause 143	Clause 153
Section 154				Clause 144	Clause 154
Section 155				Clause 145	Clause 155
Section 156				Clause 146	Clause 156
Section 157				Clause 147	Clause157
Section 158				Clause 148	Clause 158
Section 159			Clause 134	Clause 149	Clause 159
Section 160			Clause 135	Clause 150	Clause 160
Section 161	Clause 120	Clause 122	Clause 136	Clause 151	Clause 161
Section 162	Clause 121	Clause 123	Clause 137	Clause 152	Clause 162
Section 163		Clause 124	Clause 138	Clause 153	Clause 163
Section 164		Clause 125	Clause 139	Caluse 154	Clause 164
Section 165			Clause 140	Clause 155	Clause 165
Section 166	Clause 122	Clause 126	Clause 141	Clause 156	Clause 166
Section 167	Clause 123	Clause 127	Clause 142	Clause 157	Clause 167
Section 168	Clause 124	Clause 128	Clause 143	Clause 158	Clause 168
Section 169				Clause 159	Clause 169
Section 170	Clause 125	Clause 129	Clause 144	Clause 160	Clause 170
Section 171	Clause 126	Clause 130	Clause 145	Clause 161	Clause 171
Section 172	Clause 127	Clause 131	Clause 146	Clause 162	Clause 172

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Section 173	Clause 128	Clause 132	Clause 147	Clause 163	Clause 173
Section 174	Clause 129	Clause 133	Clause 148	Clause 164	Clause 174
Section 175					Clause 175
Section 176					Clause 176
Section 177					Clause 177
Section 178					Clause 178
Section 179					Clause 179
Section 180					Clause 180
Section 181					Clause 181
Section 182					Clause 182
Section 183					Clause 183
Section 184					Clause 184
Section 185	Clause 130	Clause 134	Clause 149	Clause 165	Clause 185
Section 186	Clause 131	Clause 135	Clause 150	Clause 166	Clause 186
Section 187	Clause 132	Clause 136	Clause 151	Clause 167	Clause 187
Section 188	Clause 133	Clause 137	Clause 152	Clause 168	Clause 188
Section 189	Clause 134	Clause 138	Clause 153	Clause 169	Clause 189
Section 190	Clause 135	Clause 139	Clause 154	Clause 170	Clause 190
Schedule 1	Schedule 1	Schedule 1	Schedule 1	Schedule 1	Schedule 1
Schedule 2	Schedule 2	Schedule 2	Schedule 2	Schedule 2	Schedule 2
Schedule 3	Schedule 3	Schedule 3	Schedule 3	Schedule 3	Schedule 3
Schedule 4	Schedule 4	Schedule 4	Schedule 4	Schedule 4	Schedule 4
Schedule 5	Schedule 5	Schedule 5	Schedule 5	Schedule 5	Schedule 5
Schedule 6	Schedule 6	Schedule 6	Schedule 6	Schedule 6	Schedule 6
Schedule 7	Schedule 7	Schedule 7	Schedule 7	Schedule 7	Schedule 7
Schedule 8	Schedule 8	Schedule 8	Schedule 8	Schedule 8	Schedule 8
Schedule 9	Schedule 9	Schedule 9	Schedule 9	Schedule 9	Schedule 9
Schedule 10	Schedule 10	Schedule 10	Schedule 10	Schedule 10	Schedule 10
Schedule 11	Schedule 11	Schedule 11	Schedule 11	Schedule 11	Schedule 11
Schedule 12	Schedule 12	Schedule 12	Schedule 12	Schedule 12	Schedule 12
Schedule 13	Schedule 13	Schedule 13	Schedule 13	Schedule 13	Schedule 13
Schedule 14	Schedule 14	Schedule 14	Schedule 14	Schedule 14	Schedule 14
Schedule 15	Schedule 15	Schedule 15	Schedule 15	Schedule 15	Schedule 15
Schedule 16			Schedule 16	Schedule 16	Schedule 16
Schedule 17				Schedule 17	Schedule 17

Section of the Act	Bill as Introduced in the Commons	Bill as amended in Committee in the Commons	Bill as introduced in the Lords	Bill as amended in Committee in the Lords	Bill as amended on Report in the Lords
Schedule 18	Schedule 16	Schedule 16	Schedule 17	Schedule 18	Schedule 18
Schedule 19					Schedule 19

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