HEALTH BILL

Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee

Contents

Introduction

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee to assist with its scrutiny of the Health Bill (the Bill). The Bill was introduced in the House of Commons on 14 May 2026. This memorandum identifies the provisions of the Bill that confer powers to make delegated legislation. It explains in each case why the power has been taken and explains the nature of, and the reason for, the procedure selected.

Purpose and effect of the Bill

2. The purpose of the Bill is to provide the legislative footing for the abolition of NHS England (NHSE), as announced by the former Prime Minister in March 2025 and support the establishment of a Single Patient Record (SPR). The Bill will also give effect to a number of policies that were set out in the 10 Year Health Plan and Dr Penny Dash's review of patient safety across the health and care landscape (Dash Review).

3. The Bill therefore contains provisions on a wide range of policies. It contains 89 clauses and has 12 Schedules.

Health Bill

4. The Bill abolishes NHSE as a statutory organisation and includes provision in relation to the transfer of NHSE staff, rights, liabilities and property. As a result of this abolition, a number of NHSE functions will either cease, or will be conferred on another person or body, primarily the Secretary of State or integrated care boards (ICBs).

5. The Bill transfers responsibilities for all but the most specialised commissioning functions to ICBs, including commissioning of primary medical, dental, ophthalmic and pharmaceutical services, who are best placed to integrate care as local strategic commissioners. The Bill also makes changes to dispensing doctors' rights in England, provide ICBs with more flexibility to manage pharmaceutical services access in local emergencies and streamline the pharmacy contractors appeals processes.

6. For a small number of the most specialised services, the Bill enables the Secretary of State to take on the commissioner role previously held by NHSE on a national basis. The list of these services will be prescribed in

regulations. Alongside and complementary to the Secretary of State's new commissioning role, the Bill transfers from NHSE to the Secretary of State a number of powers to arrange services, and a number of duties as to how their functions should be discharged, such as a new duty to promote innovation, and revised duties in relation to patient involvement, patient choice, and education and training, to reflect the change in Secretary of State's role from being the overseer of the system to becoming a commissioner as well. The Bill also contains powers to enable the Secretary of State to delegate functions and enter into joint working and delegation arrangements alongside a power to direct ICBs to take on delegated functions. The Bill supports joint working by amending the bodies who can be involved in local partnership arrangements under section 75 of the NHS Act 2006

7. The Bill confers NHSE's responsibilities with respect to information, including establishing information systems, to the Secretary of State. This includes a power for the Secretary of State to direct public bodies to carry out the exercise of the Secretary of State's information functions.

8. With the abolition of NHSE, the Bill sets out a direct relationship between ICBs and the Secretary of State, with the Secretary of State holding ICBs accountable for the first time and having a greater role in directly managing the system. As a result, the Bill includes a new power of direction, to enable the Secretary of State to direct ICBs about the exercise of their functions. It is intended that this direction making power will be used to require ICBs to commission services that comply with set national standards, as well as support the day-to-day management of the system. The power of direction over ICBs contains restrictions and will not be capable of being used in relation to the appointment of individuals or individual treatment decisions. It also cannot be used in a way that is inconsistent with National Institute for Health and Care Excellence (NICE) recommendations or guidance and ICBs will not have to comply with directions that are inconsistent with subsequent NICE recommendations or guidance.

9. The Bill makes provision to enable ICBs to become more strategic commissioners. Alongside taking on direct responsibility for additional commissioning functions, as outlined above, the Bill significantly simplifies a number of duties on ICBs. It reduces the complexity of the planning process by reducing the number of plans local areas must produce and removes the requirement for Integrated Care Partnerships. It also clarifies the financial duties on ICBs, meaning they are no longer responsible for achieving system balance – reflecting their role in allocating resources, and providers' responsibilities for operating within their means.

10. The Bill makes a number of changes in relation to providers, to support NHS foundation trust reform and reflect the abolition of NHSE. The Bill provides the Secretary of State with the role of overseeing the provider sector, transferring responsibility for the provider licence and trust special administrator processes from NHSE to the Secretary of State. It provides for a new process to enable the Secretary of State to convert NHS foundation trusts into NHS trusts in cases of failure. It will additionally remove the requirement for NHS foundation trusts to have a council of governors and members, allowing them to put in place more dynamic arrangements and as a consequence makes a number changes to governance of foundation trusts. It also includes a new power for the Secretary of State to limit the annual expenditure of NHS foundation trusts. It makes changes to the provider licence provisions to reflect the abolition of NHSE and expands the purposes for which provider licence conditions may be set or modified to promote or secure compliance with statutory obligations.

11. The Bill includes a power to make regulations to enable the creation of a SPR. The regulations, among other things, may confer functions on public bodies in connection with the establishment or operation of the SPR system, require information to be processed and made available to people involved in the provision of health and social care, and impose financial penalties to ensure the proper operation of the SPR system. The Bill requires the Secretary of State to undertake a consultation before regulations are made, and when making them, to have regard to the need to ensure that adequate safeguards are in place to prevent improper use of information.

12. Taking on board the recommendations of the Dash Review, the Bill includes provision to abolish Healthwatch England and remove the requirements on local authorities to arrange for certain activities to be carried out by local Healthwatch organisations, instead placing responsibility on ICBs and local authorities to undertake those activities. It also transfers the functions of the Health Services Safety Investigations Body (HSSIB) into the Care Quality Commission (CQC).

13. The Bill makes a number of changes to the medicines regulatory landscape. This includes provisions which streamline the Medicines and Healthcare products Regulatory Agency (MHRA) powers to make regulations, supporting the government's wider regulatory reform programme. The Bill will also allow the Secretary of State to establish the statutory foundation for a future medical device licensing regime in Great Britain, with detailed policy to be developed through secondary legislation following consultation.

14. The Bill includes a significant number of consequential amendments in light of the abolition of NHSE, Healthwatch England, and the transfer of HSSIB's functions into the CQC.

Summary of Delegated Powers

15. In deciding whether matters should be specified on the face of the Bill or dealt with in delegated legislation, the department has carefully considered the need:
    - to avoid too much technical and administrative detail on the face of the Bill
    - to provide flexibility for responding to changing circumstances, so that requirements can be adjusted without the need for further primary legislation
    - to allow detailed administrative arrangements to be set up and kept up to date within structures and principles that are set out in primary legislation, subject to Parliament's right to challenge inappropriate use of powers.

16. Due to the nature of the changes the Bill provides for, this memorandum takes a pragmatic approach and provides a full delegated power analysis of those powers that are new or substantively changed. Powers where the power remains the same in scope but is transferring to another body, such as an ICB or the Secretary of State, or where other minor or consequential amendments are made to an existing delegated power, are listed at Annex A.

17. The Bill contains a total of 177 powers. In the the majority of cases these are existing delegated powers being transferred from NHSE to the Secretary of State. Four of the powers in the Bill – the power to make provision consequential on the Bill, the power to restate medical devices law in Northern Ireland, the power to amend the meaning of "medical device" and the power to make further and consequential amendments relating to medical devices - include a power to amend primary legislation through secondary legislation ("Henry VIII" powers). These are all subject to the affirmative procedure.

    - The power to make provision consequential on the Bill is included to ensure that legislation continues to operate effectively, and the statute book is kept up to date. This is contained in clause 85.
    - The power to restate medical devices law in Northern Ireland confers a power on the Secretary of State to restate the body of legislation governing medical devices in Northern Ireland, including primary legislation. This is to ensure that the Northern Ireland medical devices framework remains coherent, accessible and operable following the repeal of Chapter 1 of Part 4 of the Medicines and Medical Devices Act 2021 and the replacement of the Great Britain regime with a licensing framework. This is contained in clause 80.

- The power to amend the meaning of “medical device” allows the Secretary of State to amend the definition of "medical device" in the Medicines and Medical Devices Act 2021 by regulations that is needed to keep up with rapidly evolving medical technology, particularly software, AI and combination products. A fixed definition in primary legislation could quickly become outdated and prevent the regulatory framework from keeping pace with innovation and emerging technologies. This is contained within clause 81.
- The power to make further and consequential amendments relating to medical devices allows the Secretary of State to make provision consequential on regulations establishing the new Great Britain licensing regime and regulations restating Northern Ireland law, including to primary legislation where necessary. This is contained in clause 82.

Abbreviations

18. This memorandum contains the following abbreviations and references:

the NHS Act 2006	The National Health Service Act 2006
the Health and Care Act 2022	The Health and Care Act 2022
MMDA	Medicines and Medical Devices Act 2021
CQC	Care Quality Commission
HSSIB	Health Services Safety Investigation Body
ICB	integrated care board
NICE	National Institute for Health and Care Excellence
NHSE	NHS England
SpHA	Special Health Authority
HMT	His Majesty’s Treasury
SPR	Single Patient Record
MHRA	Medicines and Healthcare products Regulatory Agency

Overview of delegated powers in the Bill

19. The Bill abolishes NHSE and transfers its functions to the Secretary of State, or the wider health system.

20. In connection with the abolition of NHSE and transfer of its functions, the Bill includes a power for the Secretary of State to transfer NHSE’s property, rights and liabilities to one or more transferee bodies, and a power for HMT to vary the way in which a relevant tax has effect in relation to anything transferred under a transfer scheme.

21. The Bill gives a series of direction making powers to the Secretary of State to direct ICBs. Some of these reflect direction making powers that NHSE currently has over ICBs; some are new (in the sense that they were not held by NHSE) and reflect the position that the Secretary of State will be directly responsible for overseeing ICBs. These powers include:

    - a power to direct an ICB to exercise any of Secretary of State's functions, and a power to direct ICBs about the exercise of their functions
    - a power of intervention in the case of ICB failure

22. To support this, the Bill provides for powers to issue guidance including on patient choice and enforcement, and on the discharge of the ICB's functions

23. Additionally, the Bill includes a power that allows for the Secretary of State to delegate functions to or work jointly with relevant bodies, local authorities, combined authorities, combined county or authorities or other persons prescribed in regulations, and a power to form joint committees and pool budgets. To support this, the Bill will transfer the power to publish guidance for relevant bodies about the exercise of their powers under sections 65Z5 and 65Z6 of the NHS Act 2006 from NHSE to the Secretary of State.

24. The Bill moves most commissioning functions to ICBs, and the Secretary of State will be responsible for commissioning services that are more effectively planned and commissioned at a national level. There is a regulation making power which may be used to set out the services that the Secretary of State will commission.

25. The Bill contains powers to support the changes to the NHS foundation trust and NHS trust landscape. These include changes to existing delegated powers of the Secretary of State, alongside conferring powers that are currently conferred on NHSE on the Secretary of State – for example, to manage the provider licence, appoint trust special administrators where there is a serious failure in an NHS trust or an NHS foundation trust and to place limits on expenditure of foundation trusts. They also include a new power for the Secretary of State to convert failing NHS foundation trusts into NHS trusts.

26. The Bill gives powers to the Secretary of State so there is appropriate financial oversight of ICBs. This includes conferring on the Secretary of State, NHSE's current powers to:

    - direct ICBs to spend a designated amount of their allocation on service integration

- give ICBs directions about their management and use of financial resources or other resources

27. The Bill provides the legislative framework for the establishment of the SPR. This creates a power for the Secretary of State to establish the SPR system via regulations. The regulations may confer functions on public authorities to set up or operate the system and require or authorise the processing or disclosure of patient information. The regulations may also confer on the Secretary of State, the CQC or a SpHA the power to impose financial penalties in specified circumstances.

28. Additionally, the Bill provides the legislative basis for the establishment of a new statutory medical device licensing regime in Great Britian. To achieve this the bill inserts new powers into the Medicines and Medical Devices Act 2021 to enable Secretary of State to make regulations to establish a medical device licensing regime. This includes three Henry VIII powers, to amend primary legislation to ensure that medical device legislation remains coherent and up to date. These regulations would be subject to the affirmative procedure.

Analysis of Delegated Powers by clause

Clause 2: Transfer schemes in connection with abolition of NHS England
Power conferred on: Secretary of State
Power exercised by: Scheme
Parliamentary Procedure: None

Context and purpose

29. The Bill abolishes NHSE, and it will therefore be necessary to transfer its property, rights and liabilities to one or more transferee bodies. This clause provides that the Secretary of State may make schemes for such transfers to the Secretary of State, an ICB, a company formed under section 223 of the NHS Act 2006, an SpHA, an NHS trust, an NHS foundation trust, a Local Health Board or any other public body.
30. A transfer scheme may, among other things: create rights or impose liabilities in relation to property, rights or liabilities transferred; make provision for shared ownership or use of property; and make provisions about the continuing effect of things done by NHSE in respect of anything transferred.

Justification for taking the power

31. It is necessary to delegate the power to make transfer schemes as it would not be practical to make specific provision in primary legislation in each case where a transfer of property and staff, and of the associated rights and liabilities, is necessary. The circumstances surrounding the abolition of NHSE, and the transfer of its property, rights and liabilities is complex and varied, so flexibility is required to accommodate requirements that may arise.
32. Delegating this power also allows for appropriate and timely consultation, where appropriate, with impacted bodies and staff and ensures transfer provisions are tailored to each transferee, protecting staff and service users.

Justification for the procedure

33. The department considers that no Parliamentary procedure is required. The schemes are concerned with administrative and operational details, and it is usual that no parliamentary procedure would attach to transfer schemes of this nature.

Clause 3: Transfer schemes under section 2: taxation
Power conferred on: HMT
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

34. Clause 3 contains the delegated power which confers on HMT the power to vary the way in which a relevant tax has effect in relation to anything transferred under a scheme made under clause 2. This includes making provision for a tax provision not to apply or to apply with modification, for anything transferred to be treated in a specified way for the purposes of a tax provision, for the Secretary of State to be required or permitted to determine anything which needs to be determined for the purposes of any tax provision relating to anything transferred or anything done for the purposes or in relation to the transfer.
35. In this clause, 'relevant tax' is defined as income tax, corporation tax, capital gains tax, value added tax, stamp duty and stamp duty reserve tax.

Justification for taking the power

36. The intention in providing HMT with this power is to ensure that any transfer of assets, rights, or liabilities be tax neutral for NHSE and the transferee. HMT has a power to vary any relevant tax to ensure that no taxes arise and that there are no changes to the tax position of either the transferee or NHSE.
37. The delegation of this power is necessary because the tax implications arising from transfers of property, rights, and liabilities cannot be fully anticipated at the point of drafting the Bill. The delegated power is required to respond to the tax implications of future transfer schemes as they arise including circumstances that cannot be foreseen at the time of the Bill's passage.
38. The scope of the power is limited to specific taxes. There is a precedent for this type of power in section 107 of the Health and Care Act 2022.

Justification for the procedure

39. The department considers the negative procedure is appropriate. The matters addressed by these regulations are administrative and operational in nature, dealing with how established tax rules should apply to the transfer of property, rights, and liabilities between NHSE and other NHS and public bodies.

Clause 8: Directions to exercise Secretary of State's functions (new clause 7B of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

40. This clause substitutes section 7B of the NHS Act 2006. It omits the reference to NHSE and broadens the scope of the power. It enables the Secretary of State to direct one or more ICBs to exercise any of the Secretary of State's functions relating to the health service, including both

health and public health functions. The directions may also stipulate restrictions on the onward delegation of those functions. Unlike the delegation frameworks set out under sections 65Z5 and 75 of the NHS Act 2006, which are entered into voluntarily, any ICB directed under this power would be legally obliged to carry out the stipulated function(s).

41. The clause also:
    - provides for this power of direction to be used transparently by obliging the Secretary of State to publish any directions made under the power as soon as reasonably practicable
    - empowers the Secretary of State to make payments to the ICB(s) in respect of the exercise of any delegated function(s)
    - provides that any rights acquired or liabilities incurred in respect of the exercise of a function(s) by an ICB(s) are enforceable against the ICB directed to exercise the function(s).

Justification for taking the power

42. The use of the power to direct ICBs to exercise the Secretary of State's functions allows flexibility, responding to changes to the models of delivery for health and public health functions and to the capability of the organisations delivering them. It also allows services to be tailored to local needs. This power may be used in conjunction with clause 11, the Secretary of State may direct an ICB to carry out a function of the Secretary of State and also direct the ICB as to how to carry out that function.

Justification for the procedure

43. Directions, which do not attract any Parliamentary procedure, allow the Secretary of State the flexibility to assign functions to individual, multiple or all ICBs, without taking up valuable parliamentary time. The procedure would allow the Secretary of State to act rapidly, including for short term arrangements.

Clause 11: General power to direct integrated care boards (new section 14Z61 of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

44. The new general power in the substitute section 14Z61 of the NHS Act 2006 will enable the Secretary of State to direct ICBs in relation to the exercise of their functions, including whether or not to exercise a power, when or how a function is (or is not to be exercised), conditions which are to be met before a function is exercised and matters to be taken into account when exercising a function. Where a function is contingent on an ICB forming an opinion, the power can be used to direct an ICB to act in a certain way, whether or not the ICB has itself formed that opinion The power can be used to direct all ICBs, or to direct individual groups of ICBs (see existing section 272(7) of the NHS Act 2006).

Justification for taking the power

45. Once NHSE is abolished, the Secretary of State will be directly responsible for overseeing all ICBs. Currently, the Secretary of State has a power to direct NHSE (in section 13ZC of the NHS Act 2006) but this power has only been used on highly technical functions and cannot be used to direct NHSE to direct ICBs. There is currently no general power for the Secretary of State to issue directions to ICBs, as to the exercise of their functions.
46. Neither is there a general power for NHSE to direct ICBs as to the exercise of their functions. NHSE can only direct ICBs with respect to their primary care functions or where it considers that an ICB is failing (or is at risk of failing) in the exercise of its functions (current section 14Z61).
47. The absence of such a power for NHSE has proven difficult in recent times, when it would have been helpful to have the power to direct ICBs to respond to emerging situations, particular circumstances or how to discharge their functions. Once NHSE is abolished and the Secretary of State takes on responsibility for the oversight of ICBs, a power to ensure that ICBs are discharging their functions effectively is required. This power will in turn assist the Secretary of State to comply with their overarching duty in section 1 of the NHS Act 2006 and their general duties in sections 1A to 1GA of that Act.

48. The power of direction is intended to be used to direct ICBs about their existing functions, such as in relation to the standards or service specifications which must be met when they commission certain services. These may vary depending on the service but are intended to ensure nationally consistent service standards, eligibility criteria or clinical pathways. Directions are the most appropriate route through which to impose these requirements, as they will enable the Secretary of State to respond to changes in the sector and beyond and implement changes more quickly than they would through regulations. The Secretary of State will also be able to set out specifications in a level of detail that would not ordinarily be included on the face of primary or secondary legislation. While an ICB may form an opinion on an issue, like a service specification, they must act in a consistent manner with any direction on the same topic. A direction on a topic, like a service specification, may be given to reduce the risk of unintended variation in health outcomes.
49. It should be noted there are also regulation making powers in the Bill, in clause 16, that will be used to set requirements related to the waiting times incurred in the exercise of ICB commissioning functions, and which protect patient choice in relation to these functions. It is appropriate for these requirements to be set out in regulations as these are rights held by patients that need to be consistently applied across the NHS.
50. The power of direction has safeguards to avoid inappropriate interventions from the Secretary of State in individual cases. The Secretary of State will not be able to use the power of direction to direct ICBs as to the appointment or employment of a particular individual or about the services to be provided to a particular individual in respect of health-related areas. Nor can the Secretary of State issue a direction about the provision of any drug, medicine or other treatment, or the use of any diagnostic technique, where that direction is inconsistent with NICE recommendations or guidance.

Justification for the procedure

51. There is no parliamentary procedure attached to the making of the direction. Directions will be made via an instrument in writing. This is consistent with other direction making powers in the NHS Act 2006. However, the Secretary of State must publish any direction as soon as reasonably practicable after giving it.

Clause 11: General power to direct integrated care boards (new section 14Z62A of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

52. This clause inserts new section 14Z62A into the NHS Act 2006. It gives the Secretary of State the power to direct an ICB, if that ICB is failing or is at significant risk of failing and that failure is or would be significant. This replaces the similar power currently held by NHSE under section 14Z61, which is being repealed.
53. ICB underperformance will, from 2026 to 2027, be measured by an NHS Oversight Framework. This Framework will allocate each ICB to one of 4 performance segments derived from scored metrics across 6 domains: allocation of resources; effectiveness and experience of care; patient safety; people and workforce; finance and productivity; and prevention and inequalities. These domains will measure both short term delivery and medium-term sustainability of the planning priorities.
54. The Secretary of State will be able to direct an ICB to stop performing some or all of its functions for such period or periods as may be specified in the direction; direct the ICB or Chief Executive to cease exercising a function; remove functions from the ICB, exercise the functions themselves, or assign them to a different ICB; terminate the ICB Chief Executive and direct the ICB chair to make a replacement appointment.

Justification for taking the power

55. This replaces a similar power which NHSE currently has in relation to ICBs. It is appropriate for the Secretary of State to take these powers as this will ensure that ICBs and their Chief Executives remain subject to a clear line of accountability, after NHSE's abolition.
56. This also protects the interests of patients and the public in enabling responsive action from the centre to ensure that communities do not receive inadequate health services.
57. It is also appropriate for these to be separate from the general power of direction over ICBs (in new section 14Z61), to make clear that they are being used in a different and unique context. Also, unlike with the general power, it is appropriate in these circumstances to be able to direct in relation to the termination and appointment of the Chief Executive.
58. As these powers will need to be used to respond to particular circumstances at particular ICBs, and to do so quickly, it would not be practical to use regulation making powers to this effect. The Secretary of State needs to be able to take action quickly and effectively in relation to particular ICBs.

Justification for the procedure

59. There is no parliamentary procedure attached to the making of the direction, which will be made via an instrument in writing. This is consistent with other direction making powers in the 2006 Act. Where the Secretary of State exercises this power, the Secretary of State must publish the reasons for doing so. In addition, where the Secretary of State intends to direct another ICB, or the chief executive of another ICB, to discharge the relevant function, the Secretary of State must consult that ICB before making the direction.

Clause 12: Commissioning functions: responsibility (amended section 3B of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

60. Section 3B of the NHS Act 2006 currently provides the Secretary of State with a power to make regulations to require NHSE to arrange for the provision as part of the health service of the following categories of services:
    - dental services of a prescribed description
    - services or facilities for members of the armed forces or their families
    - services or facilities for persons who are detained in a prison or in other accommodation of a prescribed description
    - such other services or facilities as may be prescribed.
61. Since 2012 the Secretary of State has required NHSE to arrange for the provision of these services through the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.
62. This clause substitutes section 3B. Section 3B will be reframed to set out which services the Secretary of State (as opposed to NHSE) will be required to arrange for the provision of as part of the health service. This will include:
    - services or facilities for members of the armed forces or their families
    - such other services or facilities as may be prescribed.
63. These amendments will enable the transfer of limited NHSE commissioning functions to the Secretary of State where the services are more effectively planned and commissioned by a national body. The omitted services (dental services of a prescribed description, service or facilities for persons who are detained in a prison or in other accommodation of a prescribed description, specialised services that do not need to be commissioned by a national body) will become the responsibility of ICBs.
64. Section 3B will be amended to remove the requirement to consult with NHSE as this provision will become redundant once NHSE is abolished. As the Secretary of State will seek advice as part of the usual course of action in the development of secondary legislation, the explicit requirement to seek advice before making regulations is being removed.

65. In respect of current section 3B(1)(d) services (prescribed services), the Secretary of State will continue to be required to have regard to the criteria set out at new section 3B(2): (a) the number of individuals who require the provision of the service or facility; (b) the cost of providing the service or facility; (c) the number of persons able to provide the service or facility. These requirements reflect the complexity of the services and the need to consider the operational implications of including a service in the regulations before they are so prescribed.
66. By virtue of new section 3B(3), the regulations may include provision specifying that the Secretary of State is responsible for a certain group of people for the purpose of carrying out functions in relation to advance choice documents undersection 130M(4)(a) of the Mental Health Act 1983.

Justification for taking the power

67. The power continues elements of an existing power in current section 3B of the NHS Act 2006 to make regulations in respect of commissioning requirements, although the person required to commission services under those regulations will be the Secretary of State rather than NHSE.
68. As with the current section 3B regulations, there remains a need for there to be flexibility for the Secretary of State to prescribe services or facilities which need to be commissioned nationally to respond to changes in the sector without the need for primary legislation. Changes are likely to be in response to emerging technology, the development of new services, or changing patterns of demand.

Justification for the procedure

69. The department considers the negative procedure is appropriate, which is in line with the current approach for the similar regulations applying to NHS England. We believe this provides sufficient scrutiny of the power.

Clause 16: Regulations about commissioning by integrated care boards
Power conferred on: Secretary of State
Power exercised by: Regulations and guidance
Parliamentary Procedure: Negative and none

Context and Purpose

70. Clause 16 omits sections 6E to 6G of the NHS Act 2006 and inserts new sections 14Z45A to 14Z45D into that Act.
71. Section 14Z45A will enable the Secretary of State to make regulations which impose duties on ICBs regarding waiting times for certain treatments or services. The regulations may include the arrangements ICBs must make to address non-compliance with the standards.
72. Section 14Z45B imposes a duty on the Secretary of State to make regulations to make provision about the arrangements that ICBs must make, in the exercise of their commissioning functions, to enable patients to

make choices in relation to specified treatments or services and specified aspects of those treatments or services.

73. Subsection (2) of section 14Z45B enables the Secretary of State to make further provision for the purpose of securing that ICBs protect and promote patient choice rights, where those rights arise under regulations made under subsection (1) or are described in the NHS Constitution.
74. The purpose of the power is to provide a statutory mechanism for setting out, and updating over time, requirements through which patient choice rights are to be secured by ICBs when commissioning services.
75. New section 14Z45C provides for the enforcement of regulations made under section 14Z45B. Subsections (1) to (5) of section 14Z45C enable the Secretary of State to investigate an ICB in respect of the requirements imposed by the patient choice regulations. The changes made by the Bill transfer this function from NHSE to the Secretary of State but do not alter the nature or purpose of the intervention, which continues to operate as a direction making power applicable to individual ICBs.
76. Subsection (6) places a duty on the Secretary of State to publish guidance about how the Secretary of State intends to exercise their powers in connection with patient choice enforcement, including how investigations and undertakings under sections 14Z45B and 14Z45C should operate in practice. The Bill transfers this duty from NHSE to the Secretary of State but makes no change to the substance or intended function of the duty.
77. Section 14Z45D will continue to enable the Secretary of State to make regulations creating a formal appeals system, to enable patients (or their advocates) to contest ICB commissioning decisions that directly affect their care. Regulations may make provision to enable the creation of independent panels to review cases, set rules for how appeals work (including timelines and the powers of panels), and provide for administrative support for the process.

Justification for taking the power

78. The regulation making power included in section 14Z45A replaces the power in section 6E of the NHS Act 2006, which enabled the Secretary of State to make regulations about the period within which NHSE and ICBs should be expected to deliver treatments or services. A power like this is needed to ensure that commissioners of specified services remain accountable for providing those services to patients in a timely manner.
79. The use of delegated powers for 14Z45B and 14Z45C is necessary because it ensures continuity with the existing statutory framework for patient choice. Prior to the abolition of NHSE, provisions about the patient choice requirements that ICBs must follow are also made under the regulation making powers in section 6E of the NHS Act 2006.
80. The patient choice requirements set out in regulations are inherently detailed, technical and operational in nature; while also setting out a number of patient rights that should be applied consistently across the NHS. They

concern the practical arrangements that ICBs must put in place to enable patient choice in respect of particular services or aspects of services, including how choice is offered, facilitated and communicated to patients.

81. Patient choice also operates across a wide range of NHS services, and the scope and form of choice may vary between different types of service. Regulations enable provision to be tailored by reference to specified services or aspects of services, and to be adapted over time as the health service evolves.

82. It is, therefore, necessary to retain these powers to set out the detailed arrangements through which patient choice is secured. The power does not represent an expansion of the scope of patient choice, but it provides a mechanism for giving effect to existing policy within the updated statutory framework.

83. The power is constrained in a number of ways to ensure that it is not broader than required and operates only within the defined statutory purpose. Regulations may only relate to the arrangements that ICBs must make in the exercise of their commissioning functions. In addition, section 14Z45B(2) limits further provision to the purpose of protecting and promoting patient choice rights that arise under the regulations themselves or are described in the NHS Constitution.

84. A guidance-making power is necessary in order to describe in detail the intended enforcement procedures– such as investigation steps, timescales, evidence standards, and approaches to accepting undertakings. Guidance can remain flexible and be updated promptly where new risks emerge or improvements are identified. The duty is strictly limited to publication of guidance and does not give the Secretary of State discretion to create new legal obligations.

85. The regulation-making power included in section 14Z45D enables the Secretary of State to make regulations as to the process of appealing an ICB commissioning decision for individuals personally affected by that decision. A power like this is needed to ensure the appeals process is consistent across the health system and is accessibly articulated to all patients. This power embeds and protects patient voice within the health system when exercised. It also enables ICBs to be made accountable for every commissioning decision that they take, something that is especially important as this Bill expands the scope of their commissioning responsibilities.

Justification for the procedure

86. The negative parliamentary procedure is appropriate for regulations under sections 14Z45A to 14Z45D as these statutory instruments relate to operational processes, requiring a significant level of detail. The current regulation making power these regulation making powers are replacing are also negative resolution regulations, and we think this is an appropriate level of scrutiny.

87. No parliamentary procedure is applied to guidance publication duties, consistent with the existing approach in the NHS Act 2006.

Clause 18: Transfer schemes in connection with integrated care boards
Power conferred on: Secretary of State
Power exercised by: Transfer scheme
Parliamentary Procedure: None

Context and Purpose

88. This clause gives the Secretary of State the powers to make transfer schemes in connection with ICBs; in particular where (i) an ICB is being abolished, (ii) an ICB is being established or (iii) an ICB constitution is being varied (for example, to vary the area of an ICB).
89. In the case where an ICB is being abolished, the powers must be exercised so as to secure that all the liabilities of the body being abolished (other than criminal liabilities) are transferred.
90. Transfer schemes provide a clear written record of the detail of any transfer, and this power is similar to an existing power in section 14Z28 of the NHS Act 2006, (as amended by the Health and Care Act 2022) under which NHSE can provide for the transfer of property and liabilities of an ICB via a transfer scheme.

Justification for taking the power

91. NHSE currently has a power under section 14Z28(3) of the NHS Act 2006 (as amended by the Health and Care Act 2022) to establish transfer schemes in relation to the abolition or variation of an ICB. The department considers it appropriate that this power to make such a transfer scheme is conferred on the Secretary of State. This power will enable transfer schemes to be made in connection with any future changes to ICB boundaries.
92. It is not yet known when transfer schemes in relation to particular ICBs may need to be made, so this detail cannot be provided for on the face of the Bill. Any technical details about any property, rights and liabilities that will need to be transferred would not lend itself well to regulations.
93. It is usual in health service legislation that the transfer of property, rights and liabilities of this kind are dealt with by means of transfer schemes for this reason.

Justification for the procedure

94. The department considers that no Parliamentary procedure is required, as these are detailed technical matters relating to transfers of property, rights and liabilities from one body to another. There is precedent for this approach in other clauses in this Bill (see clause 2) and in previous health service legislation (for example, under section 14Z28 of the NHS Act 2006).

Clause 22: Membership of integrated care boards

Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and Purpose

95. Schedule 1B of the NHS Act 2006 is proposed to be amended to reflect that strategic authority mayors will be able to nominate an ordinary member to sit on an ICB which covers all, or part of, their strategic authority footprint.
96. Paragraph 8(4) of this Schedule will set out that persons participating in the process for nominating ordinary members have a legal duty to have regard to the guidance the Secretary of State publishes, as to the appropriate selection of candidates.

Justification for taking the power

97. This guidance-making power is appropriate as it will ensure that the nominees of strategic authority mayors and local authorities are consistently held to appropriate standards set by the ICB.
98. This guidance will ensure any nominee has no conflict of interests before sitting on an ICB and will help to safeguard against the politicisation of membership arrangements.

Justification for the procedure

99. The content of the guidance will be detailed and technical, and subject to change, and is best suited to a guidance document which will not attract any parliamentary procedure.

Clause 25: Neighbourhood health plan, section 116A of the Local Government and Public Involvement in Health Act 2007
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and Purpose

100. Section 116A(4) of the Local Government and Public Involvement in Health Act 2007 will now ensure that local authorities and their partner ICBs have a legal duty to have regard to guidance issued by the Secretary of State when preparing a Neighbourhood Health Plan. It previously did the same in relation to the Joint Local Health and Wellbeing Strategy, which this bill is renaming to the Neighbourhood Health Plan.
101. This is important as Neighbourhood Health Plans are an important part of the overall system planning process and must be completed in a nationally consistent way.

102. It is expected that the plan will outline how the NHS, local government and partners can better co-ordinate to improve the health and wellbeing of the people in its locality, through a joined-up neighbourhood health strategy. It will also consider how local services can help realise national NHS priorities, further public service reforms, and advance improvements in adult social care outcomes and Local Outcomes Framework metrics.

Justification for taking the power

103. The Bill requires local authorities and their partner ICBs to produce a Neighbourhood Health Plan. Guidance, covering details of what should be included in the plan and the suggested form of the plan, will be necessary to reduce any unwarranted variation between the plans of each neighbourhood.

104. It is appropriate for this detail to be delivered through guidance as this level of specificity is not appropriate to be included on the face of primary legislation. Guidance is more appropriate than secondary legislation because the content of the plan is likely to evolve rapidly as the priorities and challenges for health and social care change, for example through technological change or local devolution. Issuing guidance to respond to these changes will allow the Secretary of State to ensure Neighbourhood Health Plans continue to serve local populations effectively and that all matters relevant to patients are accounted for.

Justification for the procedure

105. The use of guidance requires no parliamentary procedure. It is proportionate and reasonable not to ask Parliament to approve the guidance, given that Parliament is being asked to approve the broad duty to produce a neighbourhood plan via the primary legislation and can hold ministers to account for the production and content of the guidance.

Clause 26: NHS trust accounts

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

106. NHS trusts are subject to accounting requirements to ensure their accounts have been prepared appropriately, and to rules as to the audit of those accounts. This power enables the Secretary of State to (a) direct an NHS trust to prepare accounts for a specific period or periods (for example, for part of a financial year), (b) direct an NHS trust that those accounts prepared for a specific period or periods must be audited in accordance with the requirements of the Local Audit and Accountability Act 2014 and (c) direct an NHS trust about the content and form of those accounts and the methods and principles the accounts must be prepared in accordance with.

Justification for taking the power

107. The Secretary of State has an existing power under the current paragraph 11A of Schedule 4 to the NHS Act 2006 to direct NHS trusts as to the form in which their accounts must be kept. The Bill substitutes a new paragraph 11A to expand these powers of direction, as mentioned above, in order to align more closely with the approach being taken in respect of the accounts of NHS foundation trusts. The Secretary of State requires this delegated power as the detail of accounting methods and principles are more appropriately included in delegated legislation than on the face of the primary legislation, and to ensure that any updates to accounting methods and principles can be reflected in updated directions without the need for any amendment to primary legislation.

108. Equally, the Secretary of State needs to be able to direct individual NHS trusts about the period for which they should prepare accounts and have them audited in specific circumstances – such as, if an NHS trust is authorised as an NHS foundation trust half-way through a financial year or otherwise ceases to be during a financial year by, for example, being dissolved, or merging with another trust or foundation trust.

Justification for the procedure

109. Directions are considered to be the most appropriate form of delegated legislation here as their content will be technical, they need to be updated easily to reflect changes in accounting practices and principles, and there needs to be the flexibility to respond quickly to require an NHS trust to prepare part period accounts in the case of an NHS trust ceasing to be or becoming authorised as an NHS foundation trust. These types of delegated powers to specify details around accounting principles, accounting periods and audit in NHS legislation are usually dealt with by means of directions for these reasons.

Clause 34: Limits on expenditure of NHS foundation trusts (substitute sections 42B and 42C)

Power conferred on: Secretary of State
Power exercised by: Order and guidance
Parliamentary Procedure: None

Context and Purpose

110. Under section 42B of the NHS Act 2006, NHSE may make an order imposing a limit on the capital expenditure of an NHS foundation trust in respect of a single financial year. In doing so, NHSE must consult the NHS foundation trust before making the order and must publish each order made.

111. The Bill confers this power on the Secretary of State by means of substituting a new section 42B. The Bill also expands the power so it can be applied to the revenue expenditure of an NHS foundation trust.

112. Under section 42C, NHSE must publish guidance about the exercise of section 42B powers, including the circumstances in which a section 42B order is likely to be made, as well as the method used to determine the capital limit. NHSE must also consult the Secretary of State before it publishes any guidance under the section and must have regard to the guidance in exercising the power to make orders under section 42B.

113. In line with section 42B powers being conferred on the Secretary of State, the Bill will also substitute a new section 42C so that the accompanying guidance power will also be conferred on the Secretary of State. The Secretary of State consultation requirement will be removed, as they cannot consult themselves.

Justification for taking the power

114. The removal of ICB system control limits places greater financial risk on the department, therefore a strengthening of the department's financial control framework is deemed necessary to ensure the department is able to manage within Departmental Expenditure Limits set by HMT. NHS foundation trusts operate with a higher degree of autonomy compared to NHS trusts and thus have a level of autonomy over the way they expend their financial resources. Section 42B serves as a tool the Secretary of State can use to adhere to the budgets approved by Parliament by setting capital and revenue expenditure limits for NHS foundation trusts. The power is intended only to be used as a last resort, likely when – on the advice of the Accounting Officer – the Secretary of State is responding to a material risk of breaching Departmental Expenditure Limits.

115. Such management of the financial position is a constant effort that requires reactions to in-year events and real-time data. The subject or nature of any limit imposed under this section will therefore depend almost exclusively on the circumstances in any given year, making it necessary to retain the flexibility afforded by a delegated power. The requirement to consult the NHS foundation trust in question prior to making any order under this power will remain in place, as will the requirement to publish any order made, both of which serve as safeguards against improper use.

116. The duty on the Secretary of State to issue guidance on the use of orders under section 42B is consistent with the current duty on NHSE to issue guidance. The guidance ensures that decisions are made in a fair and transparent manner and creates certainty for NHS foundation trusts in terms of how and when the power could be used.

Justification for the procedure

117. Section 42B was introduced by section 62 of the Health and Care Act 2022, any limit imposed is done by way of order and no procedure applies. This continues to be considered appropriate for the new section 42B as the power is limited to setting capital and revenue expenditure limits on individual NHS foundation trusts to help the wider NHS stay within Departmental Expenditure

Limits, (and those expenditure limits will have been approved by Parliament); as such, it is considered that it remains appropriate that no parliamentary procedure attaches to a section 42B order as no order would be significant enough to warrant explicit approval from Parliament.

118. The section 42C guidance, as with other guidance issued under powers in the NHS Act 2006, is not subject to any parliamentary scrutiny.

119. In general, a sizeable quantity of information about DHSC's finances is made available for scrutiny, most comprehensive of which are DHSC's Annual Report and Accounts, which are laid before Parliament each year and subject to examination by the Public Accounts Committee. Parliamentarians therefore have apt opportunity to scrutinise the approach to NHS financial management.

Clause 36: Conversion of failing NHS foundation trust into NHS trust (new sections 57B and C of the NHS Act 2006)

Power conferred on: Secretary of State

Power exercised by: Order with accompanying guidance on matters to be considered in making this order.

Parliamentary Procedure: The order is a statutory instrument but attracts no parliamentary procedure. No parliamentary procedure for the guidance.

Context and Purpose

120. Section 57B is inserted into the NHS Act 2006 to confer on the Secretary of State a power to make an order to convert an NHS foundation trust into an NHS trust if it has failed to comply with a condition of its provider licence or has failed to comply with any requirement imposed on it under legislation. Subsections (3) and (4) set out the matters that the Secretary of State must consider in deciding whether to make such an order, including the seriousness of the failure, and who must be consulted before such an order is made. Section 57C then provides that the Secretary of State must publish guidance about the matters the Secretary of State proposes to take into account before making a section 57B order, including about the matters specified in section 57B(3).

Justification for taking the power

121. Currently NHSE have the powers to authorise an NHS trust to become an NHS foundation trust, but there are no powers to convert an NHS foundation trust back to an NHS trust.

122. New section 57B enables the Secretary of State to use delegated legislation to respond to circumstances where an NHS foundation trust is failing to comply with the conditions of its provider licence or with other legal requirements in a serious way by converting it back into an NHS trust. This gives the Secretary of State the option to direct it about the exercise of its functions, in a timely fashion to ensure that the provision of services by that NHS trust for its patients is maintained.

123. The guidance which must be published under section 57C will give the sector and patients and the public more detail about the kinds of matters the Secretary of State will consider in deciding whether or not to exercise this order making power.

Justification for the procedure

124. The department considers that the same procedure that attaches to an order establishing an NHS trust under section 25 of the NHS Act 2006 should attach to a section 57B order, which de-authorises an NHS foundation trust and establishes it as an NHS trust. This order, as with a section 25 order, is a statutory instrument but is not required to be laid before Parliament. This enables the Secretary of State to respond quickly to circumstances that may arise at a particular NHS trust and take swift action for the sake of the patients of the trust concerned.
125. The matters which the Secretary of State proposes to consider in deciding whether to make the section 57B order are deemed to be appropriate for inclusion in guidance, which will attract no parliamentary procedure, as they are likely to be detailed and scenario based, and not appropriately contained in a legislative vehicle.

Clause 40: Joint working and delegation arrangements (section 65Z5 of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

126. This clause adds new subsection (1A) to section 65Z5 of the NHS Act 2006 to enable the Secretary of State to enter into arrangements for any of the Secretary of State's functions relating to the health service in England to be exercised by, or jointly with, relevant bodies, local authorities, combined authorities, combined county authorities and 'such other person as may be prescribed'. It also amends subsection (3) to enable the Secretary of State to make regulations that restrict the exercise of the power to delegate or exercise the functions jointly under new subsection (1A), or to impose conditions on the exercise of that power.

Justification for taking the power

127. The delegated power provides flexibility for the Secretary of State to specify what Secretary of State functions under subsection (1A) may not be exercised jointly with or by another body, or that the power applies only to a prescribed extent in relation to certain prescribed functions.
128. The Secretary of State will need to make or amend regulations to alter the types of restrictions and conditions that apply to any arrangements, which allows for certainty and a degree of parliamentary scrutiny before

arrangements can be changed. In addition, it provides a level of flexibility to respond quickly to changing circumstances that could not be achieved if these were on the face of the primary legislation.

129. The Secretary of State may also prescribe any other person to whom the Secretary of State's functions may be delegated or with whom the Secretary of State may exercise functions jointly, to further facilitate flexibility within the system.

Justification for the procedure

130. The regulations will be subject to negative procedure. It is considered that this affords an appropriate level of parliamentary scrutiny, given the NHS-led activities addressed in the regulations, and the likely need for them to be amended from time to time. This will allow flexibility to respond to changing clinical priorities (such as public health emergencies and emerging clinical research). The ability to make and amend regulations flexibly will promote the use of delegation and joint working so that patients can receive seamless care, including between NHS and local authority-led services.

Clause 41: Arrangements between NHS bodies and local authorities
(amending section 75 of the National Health Service Act 2006)
Power conferred on: Secretary of State
Power exercised by: Regulations and guidance
Parliamentary procedure: Negative and none

Context and Purpose

131. Section 75 of the NHS Act 2006 regulation-making powers allow the Secretary of State to set out:
    a. The NHS and local authority bodies that can enter section 75 arrangements
    b. The NHS and health-related functions that NHS bodies and local authorities (respectively) can bring to a section 75 arrangement
    c. Provision relating to entry into – and the operation of – arrangements under the section.

132. Clause 41 defines combined authorities, combined county authorities and the Greater London Authority as local authorities for the purposes of section 75 (while also removing subsections 7A to 7L which treats these bodies as NHS bodies). This change enables combined authorities, combined county authorities and the Greater London Authority to enter into arrangements with NHS bodies, local authorities and other strategic authorities (so long as there is at least one NHS body involved), where they hold a relevant health-related function. Arrangements may include budgetary pooling arrangements, the sharing of resources and agreement for one of the parties to carry out the covered functions, or for them to be exercised jointly. It neither confers a new regulation-making power, nor does it amend the nature of existing powers or the procedure applicable to them.

133. The expansion of the definition of 'local authority' does, however, broaden the potential application of these regulation-making powers. Regulations may apply section 75 to all – or a subset of – local authorities, potentially including or excluding combined authorities, combined county authorities and the Greater London Authority. Regulations may also set out the health-related functions of these bodies that may be appropriately included in section 75 arrangements.

134. The clause broadens the guidance power under section 75(6). The existing power is limited in scope (it can only be issued in relation to consultation or applications for consent), and no guidance has been issued under it to date.

Justification for taking the power

135. The existing regulation making powers continue to offer the Secretary of State the flexibility to change the limits and requirements of the arrangements that can be made under the section without taking the time required for primary legislation but allowing Parliament to scrutinise any changes.

136. Expanding the existing guidance making power so that it can cover all aspects of section 75 arrangements will enable the Secretary of State to issue more comprehensive and practical guidance, the technical nature of which is not appropriate for legislation. It will allow the Secretary of State to respond more flexibly to the needs of section 75 partners, and issue updates as needed. This will support and facilitate the uptake and use of section 75 arrangements, helping to drive more consistent and effective partnership working.

Justification for the procedure

137. The clause does not change the existing mechanism. The negative resolution procedure applies for the regulation-making power in section 75. This enables legislation to be more easily adjusted to respond to differing or changing circumstances.

138. There is no parliamentary procedure for the guidance power.

Clause 42: Dispensing medical practitioners etc

Power conferred on: Secretary of State

Power exercised by: Regulations

Parliamentary procedure: negative

Context and purpose

139. The NHS Act 2006 restricts the persons with whom Integrated Care Boards may make arrangements for the provision of pharmaceutical services. Section 132 enables the Secretary of State to make regulations governing provision by medical practitioners and dentists. Clause 41 enables the Secretary of State to make regulations to provide for services to be delivered by medical practices rather than individual medical practitioners and removes the theoretical possibility to make arrangements with individual dentists, in line with current models of NHS care delivery.

140. The services that dentists provide at dental practice premises will continue to be commissioned under Part 5 of the NHS Act 2006 and will be practice-based rather than individual practitioner based.

Justification for taking the power

141. Clause 42 updates the existing power in section 132 and enables the Secretary of State to make regulations governing the provision of pharmaceutical services by medical practices rather than individual practitioners to reflect current practice. As dentists are not commissioned to provide pharmaceutical services in practice, the reference to provision by dentists is removed.

Justification for the procedure

142. The department considers that the negative procedure is appropriate, this strikes the right balance between appropriate Parliamentary scrutiny and the possible need for the regulations to be amended to respond to changing circumstances

Clause 43: Inadequate provision of pharmaceutical services

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

143. Section 133 (Inadequate provision of pharmaceutical services) of the NHS Act 2006 gives the Secretary of State the power to authorise NHSE to make alternative arrangements if a considerable number of people in a part of England experience inadequate access to pharmaceutical services. Clause 43 relaxes the legal test for making alternative provision to address the inadequate provision of pharmaceutical services owing to a disruption of services in any area of England. The Secretary of State will be able to exercise this power via time-limited directions to ICBs.

Justification for taking the power

144. Clause 43 updates the existing power in section 133 and clarifies the circumstances in which the power can be exercised, namely in the event of a disruption or likely disruption resulting in the inadequate provision of pharmaceutical services in England or an area within England. So as to not disrupt the usual market entry process this power can only be exercised by time-limited directions.

Justification for the procedure

145. The department considers directions the appropriate vehicle to enable ICBs to act quickly and flexibly to address urgent need to maintain pharmaceutical services and support patients. Directions will be time-limited to ensure the powers are used appropriately and will be published.

Clause 48: Integrated care board's funding and financial responsibilities (new sections 223GA and 223GB of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

146. New section 223GA(1) of the NHS Act 2006 creates a single, general power of direction covering the use and management of ICB finances and resources. This consolidates and replaces the existing direction-making powers of NHSE in sections 223GA(1) (expenditure on integration) and 223GB(1) (financial requirements), which are currently separate. This approach was taken to streamline the existing powers into a general power of direction and to ensure that nothing in existing section 223GA limits the exercise of powers under existing section 223GB.

Financial requirements on ICBs

147. Existing section 223GB of the NHS Act 2006 confers a power on NHSE to direct ICBs in relation to their financial management, including the imposition of limits on expenditure or resource use.
148. This power will be conferred on the Secretary of State and consolidated into new section 223GA, which provides a single, general power to give directions about the use and management of ICB financial and other resources.
149. NHSE has the power to direct an ICB to pay sums to the Secretary of State in respect of charges or other sums referable to the valuation or disposal of assets under existing section 223G(6)(b). This will now sit within scope of the broader finance direction power under new section 223GA(2)(b).
150. NHSE also has an existing power of direction under section 223G(6)(a) to direct an ICB as to the application of sums received where an existing allotment is increased or decreased. This has been omitted from new section 223G, as it falls within the scope of new section 223GA(1) and so no further express provision has been made.
151. Further, Secretary of State directions in new section 223GA may include conditions relating to the approval of the Secretary of State.
152. New section 223GA(4) also replaces and expands the previous "clawback" provisions in section 223GA(5)(b), extending the power so that it applies to failure to comply with any direction under section 223GA(1), (that relates to funds allocated under new section 223G) rather than only conditions relating to designated amounts for service integration. This would allow a broader use of the clawback power needed to help the department to meet conditions set by HMT on funding.

Expenditure on service integration

153. Under the existing framework, section 223GA(1) enables NHSE to direct ICBs that a specified ("designated") amount of their allocations under section 223G is to be used for purposes relating to service integration. Existing section 223GA(3) requires NHSE to impose conditions in relation to that designated amount, including a requirement that it be paid into a pooled fund with local authorities. Existing section 223GA(4) further enables NHSE to set conditions about spending plans and associated oversight.

154. These powers are restructured by the Bill. The power to direct ICBs in relation to service integration is transferred from NHSE and conferred on the Secretary of State and brought within the scope of the new general finance direction making power in new section 223GA(1). New section 223GA(1) enables the Secretary of State to give directions about the use and management of ICB financial or other resources.

155. The specific provision about service integration is set out separately in new section 223GB, which replaces the detailed framework currently set out in existing section 223GA(1), (3) and (4), and sets out the types of provision that may be included in directions relating to the use of designated amount for service integration (by virtue of new section 223GA(1)).

156. New section 223GB(1)(a) replaces the existing requirement for NHSE to impose a condition that a designated amount must be paid into a pooled fund. Under the new provision, the Secretary of State has a discretion to direct that some or all of the designated amount is to be paid into a pooled fund, changing from a current mandatory pooling requirement to a discretionary model.

157. New section 223GB(1)(b) replaces the existing provision relating to spending plans. These provisions enable directions to require ICBs and relevant local authorities to prepare and agree a plan for the use of the designated amount, even if no pooling takes place, to obtain approval of that plan and to meet specified objectives. New section 223GB broadly preserves the existing oversight framework in 223GA(4), while allowing it to operate whether or not funds are pooled.

<u>Justification for taking the power</u>

158. This power streamlines two direction making powers that are already in place in legislation. It introduces a general direction making power (including a clawback power in the event of failure to comply) that enables the Secretary of State to set out how ICBs should use and manage financial or other resources to ensure the effective financial oversight. It also gives the Secretary of State accountability over public funding and the ability to direct ICBs that a specified ("designated") amount of their allocation is to be used for purposes relating to service integration.

<u>Justification for the procedure</u>

159. The detailed requirements that will need to be set out in these directions, and the changing nature of those requirements means that they are best suited to

be contained in directions rather than in primary legislation or regulations. This is the same procedure that applies to the powers that are being replaced.

160. While there is no associated parliamentary procedure, the clause requires that the Secretary of State publish any direction issued under the clause as soon as reasonably practicable, which will promote transparency and accountability in relation to the Secretary State's use of this power.

Clause 52: Single patient record (new section 250E(1) and (2) of the NHS Act 2006)

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and Purpose

161. New section 250E(1) of the NHS Act 2006 provides a power for the Secretary of State to establish a SPR – a system to make patient information available to patients and people involved in the provision of health or social care in England – via regulations.

162. New section 250E(2) provides that regulations may provide for conferring functions on public authorities to set up or operate the system. The regulations may require or authorise the disclosure or other processing of patient information, or information held in connection with it, for the purpose of creating the system. They may also require or authorise such processing to make information in the system available to patients, their proxies, and healthcare providers based in the United Kingdom or the British Islands. Regulations may also confer a power on the Secretary of State, the CQC or a SpHA to impose financial penalties.

Justification for taking the Power

163. These provisions will have no impact on existing data protection legislation such as the UK GDPR or the Data Protection Act 2018. Existing safeguards and rights will be maintained. As the SPR utilises existing source records, it does not create any new sources of data. The only new data sharing gateway being created is for the purpose of establishing the system. While existing data-sharing gateways for secondary uses (for a non-direct care purpose – for example, research, planning) are maintained through a saving provision, no new gateways for such purposes can be contained in the regulations.

164. Regulations are necessary to provide for the detailed provisions regarding which information is included in a patient's SPR as well as who is provided with what information from the SPR. The SPR will bring together many existing source records and will provide access to these records on the basis of clinical relevance. This will inevitably require specific and technical rules in relation to dataflows. It will also be subject to change as the SPR is rolled out on a phased basis. Thus, the sources and relevant providers within the scope of regulations, and the detail within the regulations, will need to be regularly updated to reflect this.
165. Additionally, how access to the SPR is granted is likely to evolve based on advancements in technology along with public engagement as the SPR is implemented. This will evolve at pace and is therefore better suited to inclusion within regulations, rather than primary legislation.
166. Furthermore, the power to provide that regulations can confer powers on public authorities is appropriate to ensure that as the system develops, the SPR is operated by the most suitable public body.

Justification for the Procedure

167. The department considers the affirmative procedure appropriate. This will enable parliamentary scrutiny of any regulations before they are made.
168. Under section 250E(6), before making any regulations, the Secretary of State has a duty to consult. Additionally, under section 250E(4) the Secretary of State must have regard to the need to ensure that adequate safeguards are in place to prevent the improper use of information.

Clause 52: Single Patient Record (new section 250E(3) of the NHS Act 2006)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and Purpose

169. New section 250E(3) of the NHS Act 2006 provides that regulations may specify that the processing of information under the regulations does not breach any obligation of confidence owed by the person processing the information.

Justification for taking the Power

170. The Single Patient Record will only be successful if providers can confidently share information with the system without breaching the common law duty of confidence. It is therefore considered essential to have the ability to unequivocally specify that processing of information under the regulations does not breach any obligations of confidence. As the regulations will set out the detail regarding what information is included in a patient's SPR as well as who is provided with what information, it follows that the regulations are the best place to set out the full approach to modification of the duty of confidence. This will allow for a nuanced approach so that the duty of confidence will only be modified where it is considered necessary. Placing changes to the duty of confidence on the face of the Bill would require a blanket approach which would not be appropriate.
171. This regulation making power is modelled on existing powers contained in section 251(2)(c) of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 made under it. The approach to this delegated power is consistent with the approach across the health data law landscape to facilitate the required nuanced approach to any changes to the duty of confidence. The department considers therefore that the use of delegated legislation in this context follows existing precedent.
172. Additionally, any sharing authorised by regulations under this provision will remain subject to existing data protection legislation, including the requirement for a legal basis for sharing under UKGDPR. The department is also committed to continuing to follow the 8 Caldicott Principles in relation to confidential health and social care information.

Justification for the Procedure

173. The department consider the affirmative procedure is appropriate. This will enable parliamentary scrutiny of any regulations before they are made.
174. Furthermore, under section 250E(6), before making any regulations, the Secretary of State has a duty to consult.

Clause 52: Single Patient Record (new section 250F of the NHS Act 2006)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and Purpose

175. New section 250F of the NHS Act 2006 provides further provisions in relation to the enforcement functions exercised by the Secretary of State, the CQC or an SpHA under regulations made under 250E(2)(d).
176. Subsection (2) states that the amount of the financial penalty is to be specified in, or determined in accordance with, the regulations.

Justification for taking the power

177. It is considered appropriate for the amount of the financial penalty, or the method by which such a penalty is to be determined to be set out in regulations.
178. Setting out the amount, or determination, of the financial penalty in regulations allows flexibility to impose different penalty amounts depending on the failure itself and the body that commits it. This would allow, for example, penalties to be based on organisation size or profits. The SPR will be rolled out on a phased basis which means that the financial penalty regulations will be subject to change as the sources and relevant providers within the scope of SPR are expanded. Thus, detail within the regulations, will need to be regularly updated to reflect this.
179. Setting this detail out in regulations is consistent with the existing approach for similar financial penalty regimes in legislation such as those provided for in section 277E of the Health and Social Care Act 2012. Therefore, the department considers the use of delegated legislation in this context in not likely to be controversial and follows existing precedent.
180. Additionally, there are safeguards for anyone subject to financial penalties outlined in section 250F(3), including requirements for written notice of fines, an opportunity to make representations, and an appeal procedure to the First-Tier Tribunal.

Justification for the procedure

181. The department considers the affirmative procedure appropriate. This will provide Parliament with the opportunity to scrutinise and debate the implementation and proportionality of the financial scheme providing the appropriate level of scrutiny.

Clause 54: Health and social care information: delegation of functions (new section 251ZF of the Health and Social Care Act 2012)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

182. New section 251ZF of the Health and Social Care Act 2012 enables the Secretary of State to make arrangements for a person prescribed by regulations to exercise some or all of the functions of the Secretary of State under Chapter 1 of Part 9 (information standards), other than an excluded function, namely a function under section 251ZC of the Health and Social Care Act 2012 (public censure of relevant IT providers) and a function of making regulations.

Justification for taking the power

183. The Secretary of State needs to have operational flexibility in relation to the exercise of functions under Chapter 1 of Part 9 of the Health and Social Care Act 2012, and to have discretion to prescribe persons with whom they may make arrangements for the exercise of those functions.

Justification for the procedure

184. Regulations under this section will be subject to the negative resolution procedure. The regulations would concern the identity of the person to whom functions are to be delegated, and this may fluctuate over time. This strikes the balance between appropriate Parliamentary scrutiny and the possible need for the regulations to be amended to respond to changing circumstances This ensures transparency whilst recognising that delegation arrangements may need regular or speedy adjustment.

Clause 54: Health and social care information: delegation of functions (new section 277G of the Health and Social Care Act 2012)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

185. New section 277G of the Health and Social Care Act 2012 enables the Secretary of State to direct a public body (a body or other person whose functions are of a public nature or include functions of that nature) that exercises functions in, or in relation to, England, to exercise the Secretary of State's "relevant information functions". It also enables the Secretary of State to give directions about the exercise of those functions.

186. Subsection (4) defines "relevant information function" as any of the following functions other than a function of making regulations:

a. Functions under Chapters 1 to 3 of Part 9 of the Health and Social Care Act 2012 (including the function of establishing and operating information systems), except section 251ZC (public censure of relevant IT providers) or 267 (power to establish accreditation scheme), and information functions under certain other legislation including the NHS Act 2006, the Access to Medical Treatments (Innovation) Act 2016 and the Medicines and Medical Devices Act 2021
b. Functions exercisable in relation to the development or operation of information or communications systems in connection with the provision of health services or of adult social care in England
c. Any other functions of the Secretary of State relating to the processing of information in connection with the provision of health care or adult social care in England which are specified in regulations

Justification for taking the power

187. The Secretary of State needs to have operational flexibility in relation to the exercise of their functions, and to retain the discretion to delegate, or to not delegate, them to another person, to revoke a decision to delegate and to ensure that the most appropriate person exercises the functions, the identity of whom may fluctuate over time. The data functions may include the delivery of technical services which it may be more appropriate for a different body to undertake. In practice, the range of persons to whom these functions could be delegated would be very limited.

188. The power to direct a public body about the exercise of the functions in question is necessary in order to cover matters such as how the functions are to be exercised. Thus, the directions would contain matters of administrative or operational detail which may need to be updated regularly. There would likely be significant technical and other requirements to ensure effective delivery. This would enable the Secretary of State to cater to changing circumstances.

Justification for the procedure

189. The directions would be required to be given in writing (see section 304(12) of the Health and Social Care Act 2012), and the power would concern the question of whether an existing function should be exercised by a public body rather than the substance of the functions. The public body would be bound by any constraints which apply in relation to the exercise of those functions. Given the administrative and operational nature of the directions, Parliamentary scrutiny is considered unnecessary.

Clause 54: Health and social care information: delegation of functions (new section 277G(4) of the Health and Social Care Act 2012)

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

190. As above, the definition of “relevant information function” under section 277G(4) of the Health and Care Social Act 2012 includes functions of the Secretary of State relating to the processing of information in connection with health care or adult social care in England which are specified in regulations.

Justification for taking the power

191. The Secretary of State needs to have operational flexibility in relation to which functions (relating to the processing of information in connection with health care or adult social care) to delegate so that these can be delegated to the appropriate body depending on the context.

192. The power to make regulations provides the Secretary of State with the necessary flexibility to specify particular information functions to be delegated.

Justification for the procedure

193.The regulations would concern the specification of certain functions and section 277G enables the delegation of those functions. This strikes the balance between appropriate Parliamentary scrutiny and the possible need for the regulations to be amended to respond to changing circumstances

Clause 58: Arrangements with devolved authorities etc about information services (new section 294B of the Health and Social Care Act 2012)

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

194.Clause 58 inserts new section 294B into the Health and Social Care Act 2012 which enables the Secretary of State to direct a public body that exercises functions in or in relation to England to exercise the Secretary of State's functions under section 294A, or under arrangements under that section, as well as give that public body directions about the exercise of those functions.

195.Section 294A enables the Secretary of State to make arrangements with the Scottish Ministers (or a Scottish health body), the Welsh Ministers (or a Welsh health body), a Northern Ireland department (or a Northern Ireland health body) or a public body in the Isle of Man or Channel Islands for the provision by the Secretary of State of services or facilities in connection with the processing of information for the purposes of the Scottish health service, the Welsh health service, the Northern Ireland health service and, in relation to the Isle of Man or Channel Islands, for purposes connected with health care provision. Such arrangements may also involve the provision of services or facilities in connection with the processing of information for the purposes of the provision of social care.

Justification for taking the power

196.The Secretary of State needs to have operational flexibility in relation to the exercise of these functions, and to retain the discretion to delegate, or to not delegate, them to another person, to revoke a decision to delegate and to ensure that the most appropriate person exercises the functions, the identity of whom may fluctuate over time.

197.The power to direct a public body about the exercise of the functions in question is necessary in order to cover matters such as how the functions are to be exercised. Thus, the directions would contain matters of administrative or operational detail which may need to be updated regularly. There would likely be significant technical and other requirements to ensure effective delivery. This would enable the Secretary of State to cater to changing circumstances.

Justification for the procedure

198. The directions would be required to be given in writing (see section 304(12) of the Health and Social Care Act 2012), and the power would concern the question of whether an existing function should be exercised by a public body rather than the substance of the functions. The public body would be bound by any constraints which apply in relation to the exercise of those functions. Given the administrative and operational nature of the directions, Parliamentary scrutiny is considered unnecessary.

Clause 61: Delegation of functions under certain arrangements with devolved authorities (new section 296B of the Health and Social Care Act 2012)
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

199. Clause 61 inserts new section 296B into the Health and Social Care Act 2012 which supports delivery of arrangements made under substituted section 295 (arrangements with devolved authorities about commissioning) and substituted section 296A (arrangements with devolved authorities about education etc) of that Act. It enables the Secretary of State to direct a public body which exercises functions in, or in relation to, England to exercise some or all of the Secretary of State's functions under arrangements made with the devolved authorities under sections 295 or 296A of the Health and Social Care Act 2012.

200. Section 296B also enables the Secretary of State to give the public body directions about the exercise of those functions, including directions about the processing of information that the body obtains in exercising those functions. Subsection (2) provides that rights acquired or liabilities incurred as a result of a public body exercising functions under a direction are enforceable by or against that body (and not the Secretary of State), unless or to the extent that the direction provides otherwise, and subsection (3) requires the Secretary of State to publish any directions given under this clause.

Justification for taking the power

201. Arrangements under sections 295 and 296A are made by agreement with the relevant devolved authorities and are intended to maintain continuity and avoid disruption to established cross-border commissioning and UK-wide education and training approaches. The power in section 296B provides flexibility so that, once the Secretary of State has entered into such arrangements, operational delivery can be carried out by the most appropriate public body, but the Secretary of State would remain party to the arrangements. In practice, this ensures that where the devolved authority makes arrangements with the Secretary of State to commission a service for the purpose of their (devolved) health service, the commissioning of that service can be delegated to an appropriate body, such as an ICB.

202. The power is limited to directing a public body that exercises functions in, or in relation to England, to exercise the Secretary of State's functions under the relevant arrangements and to directing that body as to how those functions are to be exercised (including in relation to the processing of information obtained). This ensures the power to delegate is no wider than necessary to support effective delivery of agreed arrangements and enables safeguards and requirements to be imposed through directions.

Justification for the procedure

203. The power in section 296B is exercisable by the Secretary of State by way of a direction to a public body. The directions would be required to be given in writing (see section 304(12) of the Health and Social Care Act 2012). It is an administrative mechanism for allocating and controlling operational delivery of a specific arrangement.
204. The Secretary of State needs to have operational flexibility in relation to the exercise of these functions, and to retain the discretion to delegate, or to not delegate, them to another body, to revoke a decision to delegate and to ensure that the most appropriate body exercises the functions, the identity of whom may fluctuate over time. Additionally, the power to direct a public body about the exercise of the functions in question is necessary to ensure that the functions are exercised in a way which reflects any agreed arrangements with the devolved authorities
205. Given the administrative and operational nature of the directions, no parliamentary procedure is considered necessary.

Clause 64: NICE recommendations: decisions about time for compliance (amendment to section 237 of the Health and Social Care Act 2012)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and Purpose

206. Section 237 of the Health and Social Care Act 2012 enables the Secretary of State to make regulations to confer functions on NICE in relation to the giving of advice or guidance, provision of information or making of recommendations about any matter concerning or connected with the provision of NHS services, public health services or social care in England.
207. This clause amends section 237 by adding a new subsection (8A) to the effect that where under subsection (8)(b) regulations make provision requiring health or social care bodies to comply with specified recommendations made by NICE, those regulations may also set out the period within which a recommendation is to be complied with and allow for that period to be determined by either NICE or the Secretary of State.
208. This clause therefore both widens the regulation making power held by the Secretary of State in section 237 and enables provision to be made for NICE

or the Secretary of State to determine the period by which recommendations need to be complied with.

Justification for taking the power

209. The regulation making powers enable appropriate flexibility for NICE to be able to respond to constantly evolving developments in medicines, diagnostics, technologies, health and social care environments to meet the needs of the NHS, social care and wider health policy.
210. For the most part, the regulation making powers in section 237 will remain the same, with consequential amendments to remove references to NHSE.
211. The addition of subsection (8A) is required in order to allow for decisions to be made on a case-by-case basis about the period of time permitted to comply with NICE recommendations. This flexibility is particularly important in relation to funding from NHS commissioners in respect of treatments recommended by NICE, where the roll-out of certain treatments might take longer due to affordability or service delivery challenges.
212. The time period is currently determined in the recommendation and in respect of NICE technology appraisal recommendations, a provision in secondary legislation (The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013) sets out that the recommendation must be implemented in 3 months unless NICE considers it appropriate to specify a longer period.
213. Following the abolition of NHSE, the Secretary of State may be the appropriate authority to make a decision on whether the timeframe to implement a particular NICE-recommended treatment should be shorter or longer than the standard 3-month timescale.

Justification for the procedure

214. The negative procedure currently applies to any regulations made under section 237 of the Health and Social Care Act 2012. The department considers that this remains the appropriate procedure to strike a balance between scrutiny and flexibility.

Clause 66: Transfer schemes in connection with abolition of HSSIB

Power conferred on: Secretary of State
Power exercised by: Scheme
Parliamentary Procedure: None

Context and purpose

215. The Bill abolishes HSSIB. In relation to the abolition of HSSIB, it will be necessary to transfer its property, rights and liabilities to the CQC. This clause provides that the Secretary of State may make schemes for such transfers to the CQC.

216. A transfer scheme may, among other things: create rights or impose liabilities in relation to property, rights or liabilities transferred and make provisions about the continuing effect of things done by HSSIB in respect of anything transferred.

Justification for taking the power

217. It is necessary to take a power to make transfer schemes, as it would not be practical to make specific provision in primary legislation in each case where a transfer of property and staff, and of the associated rights and liabilities, is necessary. The circumstances surrounding the abolition and the transfer of HSSIB's property, rights and liabilities to the CQC could be complex and varied so flexibility is required to accommodate requirements that may arise.

Justification for the procedure

218. The schemes are concerned with administrative and operational details, and as is standard with transfer schemes in general, the department considers that no Parliamentary scrutiny is necessary.

Clause 67: Transfer schemes under section 66: taxation

Power conferred on: HMT
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

219. Clause 66 provides the Secretary of State with the power to make schemes to transfer the property, rights, and liabilities of HSSIB to the CQC.

220. This clause confers on HMT the power to vary the way in which a relevant tax has effect in relation to anything transferred under a scheme made under clause 66. This includes making provision for a tax provision not to apply or apply with modification, for anything transferred to be treated in a specified way for the purposes of a tax provision, for the Secretary of State to be required or permitted to determine anything which needs to be determined for the purposes of any tax provision relating to anything transferred or anything done for the purposes or in relation to the transfer.

Justification for taking the power

221. The intention in providing HMT with this power is to ensure that any transfer of assets, rights, or liabilities be tax neutral for HSSIB and the CQC. HMT has a power to vary any relevant tax to ensure that no taxes arise, and no changes to the tax position of either the CQC or HSSIB arise.

222. The delegation of this power is necessary because the tax implications arising from transfers of property, rights and liabilities cannot be fully anticipated at the point of drafting the Bill. The delegated power is therefore required to respond to future transfer schemes as they arise

including circumstances that cannot be foreseen at the time of the Bill's passage.

223. The scope of the power is limited to specific taxes. There is a precedent for this type of power in section 107 of the Health and Care Act 2022.

Justification for the procedure

224. The negative procedure is considered appropriate because the scope of the power is confined to ensuring that transfers made under clause 64 can proceed on a tax neutral basis and it is not considered that the regulations would need to be debated in Parliament. The power does not permit HMT to create new tax policy and is limited to technical and consequential adjustments to the way existing tax provisions apply in the specific circumstances of a transfer scheme.

225. The matters addressed by these regulations are therefore administrative and operational in nature, dealing with how established tax rules should apply to the transfer of property, rights, and liabilities between HSSIB and the CQC.

Clause 68: Reviews and investigations of commissioning

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

226. This clause amends section 48 of the Health and Social Care Act 2008 to confer a power on the Secretary of State to prescribe additional functions of the Secretary of State that the CQC may, at the request of the Secretary of State or on their behalf, review or investigate. Those additional functions are limited to the additional functions of the Secretary of State in arranging for the provision of care under the NHS Act 2006 and section 117 of the Mental Health Act 1983.

Justification for taking the power

227. The power is required to provide flexibility to reflect that commissioning functions of the Secretary of State, and responsibility for them, can change over time.

228. The power is necessary, to ensure that when the Secretary of State inherits new commissioning functions, the new functions are not automatically within section 48 scope for the CQC's special review or investigation.

229. The power only allows the Secretary of State to prescribe, via regulations, those Secretary of State commissioning functions that are mentioned in subsection (2)(ba)(i) or (ii) for CQC review. This limits the scope of the power to ensure it only covers the relevant commissioning functions of the Secretary of State.

Justification for the procedure

230. The department considers that the negative parliamentary procedure is appropriate as will this will enable sufficient scrutiny. There is precedent in taking this approach under section 46A of the Health and Social Care Act 2008.

231. Section.46A of Chapter 3 of Part 1 of the Health and Social Care Act (2008) is the duty on the CQC to review and assess the performance of English local authorities in carrying out their 'regulated care functions'. 46A(2) provides that 'regulated care functions' means such functions under Part 1 of the Care Act 2014 as may be prescribed. This is therefore a power for Secretary of State to make regulations to change the scope of CQC reviews and performance assessments of LAs, by determining which specific LA functions will be subject to review. This delegated power is subject to the negative procedure.

232. While the power to review under section 46A is somewhat different to that under section 48, it is sufficiently similar to provide a precedent that the Secretary of State may alter the scope of the CQC's review functions through negative instruments.

Clause 72: Regulations: reference to agreements and standards

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: N/A

Context and Purpose

233. The provision introduces new and amended powers to allow for ambulatory references in delegated legislation that cross-refer to external instruments that are subject to change over time.

234. For medicines, the provision makes amendments to section 2 of the Medicines and Medical Devices Act 2021 (MMDA) to provide a power equivalent to the current section 16(2) of the MMDA for medical devices. Section 16(2) allows regulations made under that section to identify relevant requirements by reference to international agreements or standards, including agreements or standards as they have effect from time to time.

235. For medical devices, the provision amends section 16 of the MMDA by substituting subsection (2) and adding new subsections 3 and 4 to introduce a targeted expansion of the current power to allow the MHRA to permit regulations made under section 15(1) MMDA to make additional ambulatory references in respect of medical devices in relation to the following circumstances:

- Regulations made under section 15(1)(a) may make references to United Kingdom standards which can be specified in a list published by the Secretary of State (in practice, the MHRA). United Kingdom standards are defined in new subsection (4) to mean standards set by the British Standards Institution or standards that are primarily developed for use in (part of) the UK. This power is in addition to the power to make references to international agreements and standards as they have effect from time to time, which is already permitted under the current wording of section 16(2) MMDA.
- Where regulations made under section 15(1) contain provision about relevant requirements (or exceptions from such requirements), those regulations may also make references to a list published by Secretary of State containing descriptions of devices and the regulatory requirements applying to them, the countries from which are eligible for an international reliance pathway (where regulations have specified the countries that are so eligible).

Justification for taking the power

236. The ability to make these ambulatory cross references is necessary to ensure that the regulatory regime remains aligned with a technical, scientific, or international framework. Requiring further domestic legislation for each update is disproportionate and risks unintentional regulatory divergence that creates uncertainty for industry. Except for a limited power to refer to international agreements and standards in relation to medical devices regulation in section 16(2), the MMDA currently does not enable ambulatory references to be made in respect of these documents in legislation. Updates to referenced documents must currently be incorporated through further legislation.

237. For medical devices, the Bill makes a targeted extension to the existing power to permit ambulatory references to specified domestic technical standard and to lists supporting the MHRA's proposed international recognition regime. The reasoning for this targeted expansion is:
    - UK technical standards: There are important technical standards issued by the British Standards Institution (BSI), or other bodies such as NICE or the Royal Colleges (where primarily developed for use in the UK). This new provision enables regulations to make references to lists published by the Secretary of State from time to time which specify these important UK technical standards. In practice, we expect the MHRA to publish these lists on behalf of the Secretary of State.

- Lists of devices and relevant regulatory requirements, from whose countries have been specified by Secretary of State in regulations as eligible for recognition (enabling those devices an exemption from certain domestic regulatory requirements) under an international reliance pathway: This allows the MHRA to set out the devices/categories of device (and the relevant international requirements that must apply to them) that are eligible for the international reliance pathway in a published list maintained by the MHRA. The Secretary of State would use secondary legislation to specify the countries outside the UK who are eligible for the international reliance pathway – this important element would not be left to the published list.

Justification for the procedure

238. This change amends the existing regulation making power, which is subject to the affirmative procedure, to enable ambulatory references to be made. The existing requirement for Parliamentary approval for regulations made under this amended regulatory making power will, therefore, remain in place, which we consider remains appropriate**.** While the effect of this change is partly determined by the content of specified lists maintained by the Secretary of State, which are not scrutinised by Parliament, this limited degree of sub-delegation is justified because the lists are confined to technical and evidence-based matters that require regular updating to reflect developments in regulation and recognised standards.
239. The international countries eligible to have their regulatory requirements recognised via the lists will have to be defined in secondary legislation approved by Parliament. The published lists reflect this policy and provide a flexible mechanism for maintaining technical detail, with decisions subject to appropriate governance, due diligence and public law safeguards.

Clause 73: Medical Devices Regulations 2002: mutual recognition agreements

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Publication of list (amendment to secondary legislation to enable SoS to publish and update a list administratively rather than specify matters in a list in regulations)
Parliamentary Procedure: N/A

Context and Purpose

240. This clause amends two definitions in the Medical Devices Regulations 2002 (MDRs) which refer to mutual recognition agreements, currently referring to a list of countries in Schedule 2 of the MDRs.

241. Currently Schedule 2 of the MDRs includes a list of countries with which the UK has concluded mutual recognition agreements (MRAs). This provision updates the two definitions in regulation 2 of the MDRs for “mutual recognition agreement” and “third country conformity assessment body”, and therefore the meaning of those phrases as they appear elsewhere in the MDRs, so that they refer to a list to be published by the Secretary of State from time to time, rather than to a list set out in Schedule 2. In practice, this provides the Secretary of State with the ability to update the list of countries with whom the UK can conclude MRAs without having to make legislation to change the Schedule**.**

Justification for taking the power

242. At present, updating this list of countries in Schedule 2 requires amendment by an affirmative statutory instrument. Therefore, the current process is that Schedule 2 is updated after MRAs have been, as a matter of fact, publicly agreed and put in place. Our view is that this update is operating as a procedural step, and therefore, requiring a legislative change is burdensome and disproportionate Further, the substance of the MRAs may be technically dense in nature requiring parliament to undertake a review previously conducted by technical experts in their designated field. This measure reduces duplicative efforts and improves the timeliness of the recognition of MRAs. Since adding a country with which the UK has signed an MRA to Schedule 2 is simply a process to update legislative references, rather than a process which is intended confer Parliamentary scrutiny over the underlying MRA, it is appropriate to allow for that process to be undertaken quickly and administratively.

243. The usual processes for agreeing and concluding such MRAs is not affected by this clause. The change provides that, in future, when a new country concludes an MRA with the UK, the references in legislation to mutual recognition agreements and third country conformity assessment bodies will automatically update once the Secretary of State adds that country to the published list. It does not amend to expand the UK’s ability to enter into MRAs nor amends the usual processes for concluding MRAs – it simply allows references in our legislation to be updated in a more timely and proportionate way once those agreements have been made under the usual processes.

Justification for the procedure

244. Not relevant

Clause 76: Consultation about medicines and medical devices regulations
Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: N/A

Context and Purpose

245. This clause amends Section 45 of the Medicines and Medical Devices Act 2021 (MMDA), which requires a public consultation to be carried out for any regulations made under Parts 1 to 4 of that Act. The clause amends the requirement to publicly consult in all cases when amending regulations under Parts 2 or 4, to provide a more flexible approach that confers on the relevant authority a duty to consult such persons as they consider appropriate, and to make minor consequential adjustments required to the MMDA to reflect the change. In relation to medical devices, the relevant authority is the Secretary of State. In relation to human medicines, the relevant authority is the Secretary of State (in relation to England, Wales and Scotland) and the Department of Health in Northern Ireland or the Department of Health in Northern Ireland and the Secretary of State acting jointly (in relation to Northern Ireland).

Justification for taking the power

246. Whilst a full public consultation will continue to be appropriate in many cases, it is not proportionate for all legislative changes. Where the change is minor, technical or limited in scope, tailored consultation with relevant stakeholders is often more appropriate and aligns with the approach for similar technical regulation making powers.

247. The current statutory duty to conduct a full public consultation can be disproportionate in many cases. In practice, it has meant that simple legislative changes have not been taken forward due to the disproportionate current consultation requirement.

248. The current duty does not tailor public consultation to the significance of the change proposed. For example, in cases of routine uplifts to ensure cost recovery as required by HM Treasury's Managing Public Money principles, there is little that consultation can meaningfully test.

249. The clause therefore does not contain any new delegated powers but instead alters the process for exercising the existing delegated powers set out in Section 45 of the MMDA Act 2021.

Justification for the procedure

250. Not relevant

Clause 77: Medicines and Medical Devices: Parliamentary procedure

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Change to negative procedure for certain powers

Context and Purpose

251. This clause amends the Medicines and Medical Devices Act 2021 (MMDA) so that certain amendments to the Human Medicines Regulations 2012 (HMRs) and Medical Devices Regulations 2002 (MDRs) are subject to the negative procedure, replacing the affirmative procedure currently required for all such regulations.

252. The HMRs set out who can sell, supply, prescribe or administer medicines. Amendments to the HMRs relate to discrete, technical, or frequently updated areas of medicines regulation, specifically:

- Changes to independent prescribing – regulations 214(3) – (6C) and Schedule 13;
- Changes to patient group directions and vaccine group directions – Schedule 16;
- Changes to professions that can supply, sell, administer via exemptions, including the medicines that can be supplied, sold or administered, and the conditions under which this can be done – Schedule 17;
- Changes to emergency administration exemption - Schedule 19; and
- Further details of sale / supply – regulation 250(6) – (9), 217C and 217CA and Schedules 15, 18 and 21.

253. We are also proposing to amend the parliamentary procedure in relation to regulation 1ZA of the MDRs, so that changes to this regulation are subject to the negative procedure. This regulation provides that certain provisions of the MDRs cease to have effect on a particular date.

Justification for taking the power

254. This clause relates to a change in how the power is exercised, rather than the taking of a new power.

255. In most cases, the exercise of regulation-making powers under the MMDA by the Secretary of State will continue to be subject to the draft affirmative procedure.

256. The provisions which would be subject to the negative procedure are narrow, technical and/or highly specific rather than substantive changes to the policy framework. Many are also subject to frequent updates in response to new products being licensed or changes in clinical practice. The types of changes associated with each group of regulations is set out in more detail below.

257. HMRs:

- Changes to independent prescribing – regulations 214(3) – (6C) and Schedule 13: amend the medicines that existing professional groups may prescribe or enable new professional groups to train as independent prescribers, reflecting changes in clinical scope of practice, licensing of medicines, or safety risks. The nature of such changes is specific, relating to a particular professional groups' scope of clinical practice, meaning they are best suited to the negative procedure. It would also be beneficial to be able to make such changes swiftly and reasonably frequently to ensure that regulations accurately reflect clinical practice as it evolves.
- Changes to patient group directions and vaccine group directions – Schedule 16: update which professional groups may supply or administer medicines through these mechanisms, and amend related requirements, to support improved access and emerging service models. The nature of such changes is specific, relating to particular professional groups' scope of clinical practice or the particulars of medicines governance, meaning they are best suited to the negative procedure. It would also be beneficial to be able to make such changes swiftly and reasonably frequently to reflect clinical practice and operational innovations as they evolve.
- Changes to professions that can supply, sell, administer via exemptions, including the medicines that can be supplied, sold or administered, and the conditions under which this can be done – Schedule 17. Schedule 17 includes a series of very specific exemptions, often including specified lists of prescription only medicines. These exemptions are important in, for example, enabling paramedics to administer medicines to patients in emergency situations, and enabling RNLI first aiders to supply necessary medicines for the treatment of sick or injured persons. Given the specific nature of these exemptions, the Secretary of State has frequent cause to update them to reflect changes in clinical practice, or the licensing of new medicines. Such changes are technical and specific in nature, thus best suited to the negative procedure.
- Changes to emergency administration exemption - Schedule 19: Schedule 19 provides a list of specific medicines (for example adrenaline and snake venom antiserum) that are subject to an exemption that enables anyone to legally administer them for the purpose of saving a life in an emergency. The Secretary of State may, from time to time, need to update the list to reflect new medicines being licensed. Such changes are technical and specific in nature, thus best suited to the negative procedure.

- Further details of sale / supply – regulation 250(6) – (9), 217C and 217CA and Schedules 15, 18 and 21. These regulations include a range of specific and technical details regarding the sale and supply of prescription only medicines. For example, in order to reflect new safety information in relation to original pack dispensing for high-risk medicines, Regulations 217C and 217CA of the HMRs enable Secretary of State to address safety risks by applying the requirement to prescribe a medicine in its original packaging, complete with health warnings, as needed. Any amendments to these regulations would be technical and specific in nature, thus best suited to the negative procedure.

258. Some of the above HMRs amendments must be coordinated with changes to legislation concerning controlled drugs, which is owned by the Home Office. Changes to that legislation are subject to the negative procedure. Using the negative procedure for the linked HMRs amendments would better align parliamentary processes.

259. MDRs:

- Amendments to Regulation 1ZA (which provides for the expiry of specified transitional provisions, including provisions relating to the recognition of CE-marked devices in Great Britain) made by negative procedure would be limited to managing the operation of those particular recognition arrangements for medical devices. This may include amending, extending or removing the existing sunset dates where necessary to maintain continuity of supply and support patient access to safe medical devices. The power is not intended to be used to make substantive policy changes or introduce significant new regulatory requirements. The regulation is narrow in scope, given it provides the continued operation of the existing regulatory regime, therefore the negative procedure provides an appropriate level of Parliamentary oversight.

Justification for the procedure

260. As detailed above, these proposals are confined to changes to the operational details that implement the existing policy framework. The department proposes to retain the affirmative procedure for any substantive policy changes, including any changes to the fundamental prohibitions in regulation 214(1) – (2) of the HMRs concerning sale, supply and parenteral administration of Prescription only Medicines. Only subsidiary detail beneath these core policy provisions—where the issues are technical and/or specific—would be subject to the negative procedure.

261. To ensure they are made safely and appropriately, such changes would require specialist input from clinicians and/or other expert stakeholders and would therefore always be subject to appropriate consultation with relevant stakeholders.

262. These proposals reflect the department and MHRA's recent experience of updating these regulations in practice and are justified by the recent Medicines and Medical Devices Act 5-year statutory review which concluded that "While the draft affirmative procedure provides strong oversight and was justified during passage as a safeguard against broad powers, operational experience now suggests that proportionality is lacking." and made a recommendation to "Amend Section 47 to permit wider use of the negative procedure for specified technical or administrative changes and retain affirmative procedure for substantive policy changes to preserve scrutiny".

Clause 78: Medical devices etc: parliamentary procedure for certain fee regulations

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Change to negative procedure for certain powers

Context and Purpose

263. The provision amends the European Union Withdrawal Act 2018 (EUWA) in respect of certain fee provisions. Currently, uplifts to existing fees made using Medicines and Medical Devices Act 2021 (MMDA) powers can be made using the negative procedure, whereas fee uplifts made using EUWA powers generally require the draft affirmative procedure. These EUWA powers are used to update fees in the Medical Devices (Northern Ireland Protocol) Regulations 2021 and the Blood Safety and Quality Regulations 2005.
264. The provision amends EUWA so that amendments to fee provisions in the Medical Devices (Northern Ireland Protocol) Regulations 2021 and the Blood Safety and Quality Regulations 2005 can be made using the negative procedure. In general, the provision streamlines the process for routine fee updates made using EUWA powers, so uplifts to existing fees charged by the MHRA to maintain cost recovery for unchanged functions do not automatically require the draft affirmative procedure.

Justification for taking the power

265. This clause relates to a change in how the power is exercised, rather than the taking of a new power.
266. This change would align the scrutiny approach more closely with the MMDA fees framework, recognising that these instruments are administrative in nature—updating charges to ensure the regulator can recover the reasonable costs of delivering unchanged functions—rather than introducing new duties, new fee models or new categories of charge. Any fee uplifts can only be made to ensure cost recovery, as required by HM Treasury's Managing Public Money principles.

Justification for the procedure

267. The change would reduce delay in making and communicating such adjustments, while maintaining appropriate safeguards through the SI framework (including publication of the cost basis for any uplift) and retaining the draft affirmative procedure for substantive changes such as new chargeable functions, material changes to charging structure, or amendments with significant policy effects.

Clause 79: Medical devices regulations: Great Britain

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Affirmative Procedure

Context and Purpose

268. The clause inserts a new Chapter A1 into Part 4 of the Medicines and Medical Devices Act 2021 (MMDA), to create new powers for the Secretary of State to make "medical devices regulations" for Great Britain. The purpose of the powers is to enable the establishment of a new licensing regime for medical devices, replacing the current regulatory regime. The regulations may require a product licence before a medical device may be supplied or advertised and may require a personal licence before a person may manufacture, import, wholesale deal in, or conduct clinical investigations relating to medical devices. The regulations may also make provision about the grant and administration of licences, licence conditions, duration and renewal, variation, suspension, revocation and transfer, public health exemptions, registers of licences, offences, enforcement and fees.
269. Great Britain's current medical devices framework is principally contained in the Medical Devices Regulations 2002 ("the MDRs"). The MDRs are derived from a regulatory model based on conformity assessment, product certification and post-market surveillance. Under that regime, many regulatory requirements are prescribed in detailed legislation, and compliance is assessed for most medical devices through third-party Approved Bodies. This has become increasingly complex and difficult to adapt quickly in response to innovation, technological change and developing clinical evidence.
270. The new licencing model enables the establishment of a different regulatory model under which market access may be determined through licences granted by the Secretary of State. This will preserve the ability of the regulator to respond rapidly to advances in technology, manufacturing processes, clinical practice and international standards, whilst retaining appropriate safeguards.
271. The statutory licensing authority will retain full responsibility for final regulatory decisions on medical devices.
272. New section 14A(1) enables the Secretary of State to make regulations to provide that specified activities relating to medical devices may only be carried out under a licence.

Justification for taking the power

273. The clause does not itself set out detailed regulatory requirements for the licensing of medical devices. It confers powers on the Secretary of State to establish and operate a licensing regime through secondary legislation which is considered appropriate due to the range of detailed licencing requirements that may be required.

274. Medical devices range from low-risk products to high-risk products, and include general medical devices, in vitro diagnostic devices and software and AI technologies. The appropriate regulatory requirements for such products will vary according to factors such as device type, risk classification, intended purpose, manufacturing process, clinical context and emerging evidence. The supporting regulatory framework must therefore be capable of being adapted in response to scientific, technological, safety and international regulatory developments.

275. The department recognises that the proposed power is broad and has therefore included significant constraints on the face of Bill, setting clear parameters for the delegated power. It identifies the core regulated activities that may be prohibited unless authorised by a licence: supply or advertising of a medical device, manufacture, importation, wholesale dealing, and the carrying out of clinical investigations. It also distinguishes between product licences and personal licences, defining the broad purpose of each form of licence on the face of the primary legislation. The intention is that the primary legislation establishes the fundamental structure, objectives and constraints of the licensing regime, while regulations provide the detailed technical requirements necessary for its operation.

276. The department recognises that regulations made under this power may create offences. This is considered necessary because the detailed licensing requirements, licence conditions and other obligations that may apply under the licensing regime cannot be specified exhaustively on the face of the Bill and will depend on the detailed design of the regime. The power to create offences is therefore limited to securing compliance with requirements imposed under the licensing framework established by the Act. In addition, the Bill specifies the maximum penalties that may be imposed and regulations creating offences will be subject to the affirmative procedure.

277. The powers are constrained by the existing safeguards in the MMDA. In exercising the powers, the Secretary of State must act consistently with the overarching objective of safeguarding public health, having regard to the safety and availability of medical devices and the attractiveness of the United Kingdom as a place in which to research, develop, manufacture and supply medical devices. Regulations would also be subject to the consultation requirements in section 45 of that Act and, in the case of regulations establishing the licensing regime, the draft affirmative procedure.

278. The introduction of a new licensing regime may require amendments to existing primary and secondary legislation which currently refer to, or operate by reference to, the existing medical devices regulatory framework. The Bill therefore includes a separate consequential amendment power in clause 79, with new section 43. Given such consequential amendments may affect primary legislation, that power contains a Henry VIII provision. The department considers that approach necessary because it is not feasible to identify in advance every consequential amendment that may be required across the statute book once the detailed licensing regulations have been developed. The power is limited to provision that is consequential on the exercise of the licensing powers.
279. The department considers that delegated legislation is necessary and appropriate. It allows Parliament to establish the framework, objectives and limits of the licensing regime in primary legislation, while enabling the detailed and technical requirements governing the operation of the regime to be developed, consulted upon and updated through secondary legislation. This approach is consistent with the existing medical devices framework, under which the detailed conformity assessment and certification requirements are set out in the Medical Devices Regulations 2002 (S.I. 2002/618) rather than on the face of primary legislation.
280. The department has considered whether this provision could be regarded as a skeleton power. The department does not consider that to be the case, because the bill itself establishes the principal features and parameters of the licensing framework and clearly contemplates the architecture of the future regime. In particular, the bill establishes that the regime is to be based on licensing rather than the conformity assessment model which underpins the current framework, identifies clearly the kinds of licences that can be issued and the prohibitions that will be central to the regulations, details regarding the variation, suspension, revocation and transfer of licences, and sets out the kind of licence conditions that can be imposed. The bill also preserves the application of wider provisions of the MMDA, including the post-market surveillance and enforcement framework in sections 21 to 24.
281. The department therefore considers that the Bill establishes the core policy framework, objectives and limits of the licensing regime, while leaving the detailed and technical requirements necessary for its operation to secondary legislation. This approach is consistent with the existing structure of Part 4 of the MMDA, under which primary legislation establishes the overarching framework for the regulation of medical devices while leaving detailed regulatory requirements to secondary legislation.

Justification for the procedure

282. Regulations made under this clause will be subject to the affirmative procedure. The power enables the establishment of a new licensing regime for medical devices and creates a framework under which specified activities relating to medical devices may be prohibited unless authorised by a licence. The exercise of the power will therefore determine the circumstances in which medical devices may be supplied, advertised, and determine the circumstances in which a person can manufacture, import, wholesale deal or conduct clinically investigations in Great Britain, and will establish the conditions and requirements applicable to the grant, maintenance, suspension and revocation of licences.
283. The department notes that the wider package of provisions includes consequential amendment powers capable of amending primary legislation where necessary to implement the licensing framework. Those powers are also subject to the affirmative procedure, ensuring that Parliament has the opportunity to scrutinise any exercise of Henry VIII powers.
284. The department considers the affirmative procedure appropriate because these regulations will establish the substantive architecture of the new licensing regime and will make policy choices that have significant implications for patient safety, the availability of medical devices and the operation of the medical technology sector. The regulations will also replace elements of the existing conformity assessment certification framework with a different authorisation model. Given the significance of those policy decisions and their potential effects on manufacturers, importers, distributors, healthcare providers and patients, it is appropriate that the regulations should be subject to debate and approval by both Houses of Parliament before they may come into force.
285. The affirmative procedure is consistent with the current approach for the medical devices regulatory framework. Regulations under section 15 of the MMDA are generally subject to the affirmative procedure, and regulations establishing the current regime under the MDR are likewise subject to affirmative parliamentary scrutiny.

Clause 80: Power to restate medical devices law in Northern Ireland
Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Affirmative Procedure

Context and Purpose

286. This clause inserts a new Chapter A2 into Part 4 of the Medicines and Medical Devices Act 2021 (MMDA). It confers a power on the Secretary of State to restate the body of legislation governing medical devices in Northern Ireland. The licensing regulations made under new section 14A will extend and apply in Great Britain only, as Northern Ireland is subject to EU legislation for medical devices, under the Windsor Framework. The power applies to legislation that will continue to govern medical devices in Northern Ireland following the introduction of the new Great Britain licensing regime, including legislation that is currently contained in the Medical Devices Regulations 2002, the Medical Devices (Northern Ireland Protocol) Regulations 2021 and relevant assimilated EU law.

287. The purpose of the power is to ensure that the Northern Ireland medical devices framework remains coherent, accessible and operable following the repeal of Chapter 1 of Part 4 of the MMDA and the replacement of the Great Britain regime with a licensing framework. The power enables the Secretary of State to consolidate, restate and modernise the drafting of retained Northern Ireland legislation without changing its substantive effect except to the limited extent necessary to resolve ambiguities, remove anomalies or improve clarity and accessibility. It is not intended for, and not drafted to allow, substantive policy reform in Northern Ireland.

Justification for taking the power

288. The legislative framework applying in Northern Ireland is complex. It consists of domestic legislation, assimilated EU legislation and amendments introduced to implement the Windsor Framework. As the Great Britain regime moves to a different regulatory model, there is a significant risk that provisions applying solely to Northern Ireland are lost or become fragmented, difficult to navigate and increasingly difficult to maintain.

289. The department therefore considers it appropriate to take a delegated power enabling the law to be restated and consolidated. The exercise is legislative and technical in nature and is not suitable for primary legislation. It may require extensive amendment, reorganisation and modernisation of drafting across a large body of legislation.

290. The power is constrained. Section 14K(4) limits changes to those necessary to resolve ambiguities, remove doubts or anomalies, or improve clarity and accessibility. It is not intended as a power to make substantive policy changes to the Northern Ireland regulatory framework.

291. The power includes a Henry VIII element because regulations may modify enactments. The department considers this necessary because the legislation to be restated is contained across a number of enactments and instruments, some of which are primary legislation or legislation with equivalent status. Without this power, it would not be possible to produce a coherent restatement of the Northern Ireland framework. The power is limited to legislation relating to medical devices in Northern Ireland and may only be exercised for the specific purposes set out in section 14K(4).

Justification for the procedure

292. Regulations made under this power will be subject to the affirmative procedure. This is intended to allow sufficient Parliamentary scrutiny, given the power permits amendment of primary legislation and other enactments as part of a substantial exercise to restate and consolidate the Northern Ireland medical devices framework.

Clause 81: Power to amend meaning of "medical device"

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Affirmative Procedure

Context and Purpose

293. The clause inserts a power into section 42 of the Medicines and Medical Devices Act 2021 (MMDA), allowing the Secretary of State to make regulations about the meaning of "medical device" for the purposes of Part 4 of the MMDA.

294. The definition of a medical device operates at the centre of the regulatory framework. Developments in technology, including software, artificial intelligence and drug-device combination products, create circumstances in which novel products may not fit neatly within existing statutory definitions and updates are required.

Justification for taking the power

295. The statutory boundary between medical devices, software, artificial intelligence systems, diagnostics and other health technologies is increasingly complex. A detailed and exhaustive definition on the face of primary legislation risks becoming out of date quickly and could impede the ability of the framework to respond to technological developments to ultimately protect patient safety.

296. A delegated power allows Parliament to establish the overall framework while enabling future refinement of the definition where necessary, to maintain regulatory effectiveness and alignment with technological developments.

297. The power expressly permits amendment by regulations of section 42 of the MMDA itself and therefore constitutes a Henry VIII power. This is justified because the definition of a medical device is a highly technical matter that may require amendment in response to developments in science, technology and international regulatory practice.

Justification for procedure

298. Regulations made under this power will be subject to the affirmative procedure, which is deemed to be appropriate because any amendment to the statutory definition of a medical device could affect the scope of the entire regulatory framework and the categories of products falling within regulation.

Clause 82: Further and consequential amendments relating to medical devices

Power conferred on: Secretary of State for Health and Social Care
Power exercised by: Regulations
Parliamentary Procedure: Affirmative Procedure

Context and Purpose

299. Clause 82 replaces the existing consequential provision power in section 43 of the Medicines and Medical Devices Act 2021 (MMDA) and confers powers on the Secretary of State to make provision consequential on regulations establishing the new Great Britain licensing regime and regulations restating Northern Ireland law.
300. The power enables consequential amendments across legislation in England and Wales, Scotland and Northern Ireland to ensure that the wider statute book continues to operate effectively following introduction of the licensing regime and the restatement of Northern Ireland legislation.

Justification for taking the power

301. The medical devices framework is referred to throughout a wide range of UK and devolved legislation. It is not currently possible to identify every consequential amendment that may be required once the detailed licensing regulations and Northern Ireland restatement regulations have been developed.
302. A delegated power is therefore necessary to ensure that appropriate consequential amendments can be made efficiently as part of implementation. The power is limited to provision that is consequential on regulations made under the substantive powers.
303. The power expressly permits amendment of Acts of Parliament, Acts of the Scottish Parliament, Acts of Senedd Cymru, and Northern Ireland legislation. This is justified because consequential amendments may be required across multiple legislative systems within the United Kingdom and it would not be practical to identify exhaustively in advance every amendment that may be necessary.

Justification for procedure

304. Regulations made under this power will be subject to the affirmative procedure. This reflects the fact that consequential changes in this area may be more fundamental, and may amend primary legislation, and introduces a significant safeguard on the exercise of the power than would usually be the case for consequential amendment powers.

Clause 85: Power to make consequential provision

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Affirmative where amending, repealing or revoking primary legislation; otherwise negative

Context and Purpose

305. This clause confers a power on the Secretary of State to make provision that is consequential on this Bill.
306. Regulations that make consequential provision may amend, repeal, or revoke provision made by primary legislation (including Acts or Measures of Senedd Cymru, Acts of the Scottish Parliament or Northern Ireland legislation) passed before, or later in the same session of Parliament as this Bill, and any provision made under such legislation.
307. Amending, revoking, or repealing primary legislation must be subject to the affirmative procedure; amendments to any other legislation are subject to the negative procedure.
308. This power may be needed to give effect to the provisions in and made under the Bill.

Justification for taking the power

309. This power may only be exercised to make provision that is consequential on this Bill. This power is required to enable consequential amendments to secondary legislation and it is standard practice to make such amendments through secondary legislation.
310. The power also provides for consequential amendments to primary legislation, because, although every effort has been made to identify and make provision in the Bill for such amendments, the scope and breadth of the Bill and the interconnection between healthcare legislation and other primary legislation (in terms of bodies or terms that are established or defined in healthcare legislation but then referred to across the legislative landscape) increases the possibility that further consequential amendments will be needed to primary legislation to give effect to the Bill and ensure coherence across the legislative landscape.
311. The department considers that it would therefore be prudent for the Bill to contain a power to make consequential amendments to primary legislation by means of secondary legislation.

Justification for the procedure

312.Any regulations made under this power are subject to the negative procedure, or the affirmative procedure where they are used to amend primary legislation. Insofar as this power is used to amend primary legislation, it is a Henry VIII power. Any regulations amending secondary legislation will be subject to the negative procedure as the changes will be consequential, are unlikely to be substantive and will be aimed at ensuring the coherence and effectiveness of the provisions in that secondary legislation. The affirmative procedure is considered appropriate for regulations made under this clause which amend primary legislation, so that any changes to primary legislation can be debated and approved in both Houses of Parliament.

Clause 88: Commencement

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: None

Context and Purpose

313.Clause 88 contains a power for the Secretary of State to bring into force provisions of the Bill by regulations (other than clauses 85, 87, this clause and clause 89 which come into force on Royal Assent and clauses 69 and 72 to 78 which come into force 2 months after Royal Assent). Different days may be appointed for different purposes and, in respect of clause 71 or Schedule 11, different days may be appointed for different areas.

Justification for taking the power

314.It is necessary for different provisions of the Bill to be commenced at different times to enable preparations to be made for the abolition of bodies provided for in the Bill, for staff to be consulted where they may transfer between bodies by means of transfer scheme, and for there to be flexibility in terms of how the significant changes across the health and social care sector are implemented, and to ensure the changes made by the Bill are implemented efficiently and effectively.

315.Clauses 69 and 72 to 78 come into force at the end of the period of two months beginning with the day on which this Act is passed as per routine Parliamentary commencement timings. Commencing clause 69 at this point will enable the extended time limit to operate as soon as possible to help to protect patient safety. The new time limit for bringing proceedings will apply only to offences committed after commencement of clause 69. Commencing clauses 72 to 78 at this point will enable the streamlining of regulatory reform measures as soon as possible.

316.The abolition of Local Healthwatch arrangements under clause 69 and Schedule 11 will bring in a new framework, where each local authority and integrated care board will have increased responsibilities for gathering patient feedback. The implementation of these provisions will be implemented locally, with a transition from the current system where there is a Local Healthwatch organisation for each local authority. It is therefore appropriate for the commencement power to permit different days to be appointed for different areas, to provide flexibility to bring the changes into force on a phased basis where necessary, reflecting that local circumstances and readiness may differ between areas.

Justification for the procedure

317.As usual with commencement powers, regulations made under this clause are not subject to any parliamentary procedure. Parliament has approved the principle of the provisions to be commenced by enacting them and commencement by statutory instrument enables the provisions to be brought into force at a convenient time and in an orderly manner.

Schedule 1: Conferral of primary care functions on ICBs etc

Paragraph 7, 19, 35 and 54 of Schedule 1: Performers Lists
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

318. Under sections 91, 106 and 123 of the NHS Act 2006, NHSE currently has powers to establish and maintain a list of health care professionals of a specified description to perform primary medical, dental and or ophthalmic services. These sections also confer powers on the Secretary of State to make regulations that set out the eligibility for inclusion on a list, the grounds to impose conditions on performers and the details of suspension and removal from a list. Section 147A of the NHS Act 2006 also provides the power to make similar regulations for pharmaceutical performers. At present, this power has not been exercised but as pharmacies deliver more clinical services it is envisaged such a list may become necessary.
319. The Bill amends the NHS Act 2006, transferring the NHSE powers of establishing and maintaining relevant lists under sections 91, 106, 123 and 147A to the Secretary of State (or the Secretary of State or an NHS body in the case of the pharmaceutical performers list the flexibility in regulations to appoint an NHS body to prepare, maintain and publish such a list will enable the Secretary of State to give this duty to the best-placed NHS body, and adjust which body that is as needed).
320. Currently NHSE have the power to impose conditions on performers on grounds of fraud and efficiency. The Bill extends the purpose for which the regulation-making powers can be exercised so that the Secretary of State will also be able to impose conditions on the grounds of suitability and to address inappropriate conduct.

Justification for taking the power

321. The flexibility of secondary legislation is required as the Performers Lists framework involves detailed technical and administrative matters, that can require frequent amendment, including changes to which health body is charged with carrying out statutory functions. For example, following wider NHS organisational changes, responsibility for the operational delivery of certain functions may transfer from one health body to another, requiring corresponding amendments to the regulations. This will guarantee that the list can continue to be maintained in a timely and effective manner to ensure patient safety.

322. The Secretary of State also requires the flexibility to delegate the operationalisation of these functions to appropriate health bodies, using delegation powers set out in sections 65Z5 to 65Z7 of the NHS Act 2006 as amended in this Bill. Where necessary, the details of any such delegation will be set out in the Performers List Regulations. This provides flexibility to quickly amend which body is responsible for the operationalisation of a particular function in response to future changes, where necessary to maintain patient safety and effective regulation. For that reason, it would be inappropriate to prescribe these arrangements in primary legislation.

Justification for the procedure

323. The negative procedure currently applies to regulations made under sections 91, 106 and 123 of the NHS Act 2006 as well as regulations made under section 147A. The Secretary of State is already responsible for the secondary legislation for the Performers Lists in accordance with sections 91, 106, 123 and 147A. Parliament has therefore previously approved the use of the negative procedure when conferring the regulation making powers on the Secretary of State, and this remains the appropriate procedure.

Paragraph 39: NHS Act 2006 new section 126(8A)(b)) – Power conferred on Secretary of State to prescribe who integrated care boards are responsible for

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

324. Currently, NHSE is responsible for making arrangements for the provision of pharmaceutical services to persons in England. The Bill will transfer this duty to ICBs to arrange such provision to people for whom ICBs have responsibility through consequential amendments to sections 126(1) and 126(3) of the NHS Act 2006, subject to regulations made by the Secretary of State.

325. New sub-section (8A) is added to provide a clarification about who an ICB has responsibility for. These are people for whom ICBs have core responsibility, as specified in section 14Z31(8A)(a) but also any other people as may be prescribed (8A)(b). New sub-section (8A)(b) therefore gives the Secretary of State the power to prescribe, by way of regulations, further categories of people for whom an ICB has responsibility.

Justification for taking the power

326. The power conferred on the Secretary of State in new section 126(8A)(b) enables the Secretary of State to prescribe a further category of people for whom ICBs are responsible to ensure they receive

sufficient drugs, medicines and listed appliances and can access other services provided as part of the national framework for pharmaceutical services. This will help ensure people who do not live in the area of the ICB can access pharmaceutical services at or from pharmacies located in the ICB area. This aims to preserve freedom for people in England to choose which pharmacy to receive services from, including distance selling pharmacies who provide services nationally, or a pharmacy near a person's workplace rather than their home. Taking a power to do this by way of regulations enables there to be flexibility built into the system to respond to changing needs in the sector.

Justification for the procedure

327. The department considers that the negative procedure is appropriate. During the Bill's passage, Parliament will have the opportunity to consider the substance of the duties being placed on ICBs in relation to the provision of pharmaceutical services and so the department does not consider that these regulations would need to be subject to the affirmative procedure in setting out further detail about a particular aspect of these duties. Furthermore, the affirmative procedure would not be appropriate as these regulations would not lead to significant policy changes but instead would be made to ensure the smooth running of, and allow for more flexibility in the provision of pharmaceutical services within, the framework already established under existing legislation. Equally, the regulations may need to be amended to reflect necessary changes to who ICBs should be responsible for, and so the negative procedure strikes the right balance between scrutiny and flexibility. This approach is consistent with the approach taken under section 14Z31 (in respect of regulations making provision about persons who ICBs have responsibility for).

Paragraph 40: NHS Act 2006 new section 127(3A)(b) – Power conferred on Secretary of State to prescribe who integrated care boards are responsible for

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

328. Currently the Secretary of State can direct NHSE to arrange provision of additional pharmaceutical services throughout England. The Bill will give the Secretary of State power to direct ICBs to make such arrangements for persons the ICB is responsible for through consequential amendments to sections 127(1) and 127(2) of the NHS Act 2006.

329. New sub-section (3A) is added to provide a clarification about who an ICB has responsibility for. These are people for whom ICBs have core responsibility, as specified in section 14Z31(3A)(a) but also any other people

as may be prescribed (3A)(b). New sub-section (3A)(b) therefore gives the Secretary of State the power to prescribe further categories of people for whom an ICB has responsibility by way of regulations.

Justification for taking the power

330. The power conferred on the Secretary of State in new section 127(3A)(b) enables the Secretary of State to prescribe a further category of people for whom ICBs are responsible to ensure they can access additional pharmaceutical services such as vaccination services. This will help ensure people who do not live in the area of the ICB can access the full range of pharmaceutical services at or from pharmacies located in the ICB area. This aims to preserve freedom for people in England to choose which pharmacy to receive services from, including distance selling pharmacies who provide services nationally, or a pharmacy near a person's workplace rather than their home. Taking a power to do this by way of regulations enables there to be flexibility built into the system to respond to changing needs in the sector.

Justification for the procedure

331. The department considers that the negative procedure is appropriate. During the Bill's passage, Parliament will have the opportunity to consider the substance of the duties being placed on ICBs in relation to the provision of pharmaceutical services and the department does not consider that these regulations would need to be subject to the affirmative procedure in setting out further detail about a particular aspect of these duties. Furthermore, the affirmative procedure would not be appropriate as these regulations would not lead to significant policy changes but instead out be made to ensure the smooth running of, and allow for more flexibility in the provision of pharmaceutical services within, the framework already established under existing legislation. Equally the regulations may need to be amended to reflect necessary changes to who ICBs should be responsible for, and so the negative procedure strikes the right balance between scrutiny and flexibility. This approach is consistent with the approach taken under section 14Z31 (in respect of regulations making provision about persons who ICBs have responsibility for) and the regulation making power under new section 126(8A)(b).

Paragraph 42: NHS Act 2006 revised section 129 – Power conferred on Secretary of State to make regulations for the pharmacy market entry system and for integrated care boards to operate this

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

332. Paragraph 42 of Schedule 1 changes references to provision of pharmaceutical services 'at' or 'from' premises to provision of pharmaceutical services 'at or from' premises for the purpose of regulations made under section 129. These amendments bring the NHS Act 2006 into line with the Medicines Act 1968 in clarifying that pharmaceutical services may take place at a pharmacy premises or from a pharmacy premises. This better reflects current practice, for example the delivery of medicines from distance selling pharmacy premises that were dispensed at the premises.

Justification for taking the power

333. The powers restate existing powers in section 129 whilst bringing the language used in the NHS Act 2006 in line with the Medicines Act 1968 to reflect the reality of the modern pharmacy operational model. Many pharmacies offer services remotely and medicines can be either collected at a pharmacy premises or delivered from a pharmacy to the person's home address. Amending the scope of this power to include delivery of pharmaceutical services from a pharmacy will allow continued development of modern pharmaceutical practice.

Justification for the procedure

334. This does not confer new powers on the Secretary of State but retains the existing powers. The negative procedure is currently used when any such regulations are made and the department considers that this remains appropriate.

Paragraph 46: NHS Act 2006 new section 134(2A)(b) – Power conferred on Secretary of State to prescribe who integrated care boards are responsible for

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

335. Currently, NHSE may establish pilot schemes. The Bill will enable ICBs to establish pilot schemes through consequential amendments to sections 134(1) and 134(2) of the NHS Act 2006. Amendments to section 134(2)(b) specify that such pilot schemes will provide local pharmaceutical services to people for whom the ICB establishing the pilot scheme is responsible.

336. New sub-section (2A) is added to provide a clarification about who an ICB has responsibility for. These are people for whom ICBs have core responsibility, as specified in section 14Z31(2A)(a) but also any other people as may be prescribed by regulations made under subsection (2A)(b). New sub-section (2A)(b) therefore gives the Secretary of State the power to, by

way of regulations, prescribe further categories of people for whom an ICB have responsibility.

Justification for taking the power

337. The power conferred on the Secretary of State in new section 134(2A)(b) enables the Secretary of State to prescribe in regulations a further category of people for whom ICBs are responsible to ensure they can access local pharmaceutical services commissioned under a pilot scheme. This will help ensure people who do not live in the area of the ICB can access local pharmaceutical services at or from pharmacies located in the ICB area. On occasions where pilot schemes have been established, this aims to preserve freedom for people in England to choose which pharmacy to receive services from, including distance selling pharmacies who provide services nationally, or a pharmacy near a person's workplace rather than their home. Taking a power to do this by way of regulations enables there to be flexibility built into the system to respond to changing needs in the sector.

Justification for the procedure

338. The department considers that the negative procedure is appropriate. During the Bill's passage, Parliament will have the opportunity to consider the substance of the duties being placed on ICBs in relation to the provision of pharmaceutical services and the department does not consider that these regulations would need to be subject to the affirmative procedure in setting out further detail about a particular aspect of these duties. Furthermore, the affirmative procedure would not be appropriate as these regulations would not lead to significant policy changes but instead would be made to ensure the smooth running of, and allow for more flexibility in the provision of pharmaceutical services within, the framework already established under existing legislation. Equally the regulations may need to be amended to reflect necessary changes to who ICBs should be responsible for, and so the negative procedure strikes the right balance between scrutiny and flexibility. This approach is consistent with the approach taken under section 14Z3 (in respect of regulations making provision about persons who ICBs have responsibility for) and the regulation making powers under new sections 126(8A)(b) and 127(3A)(b).

Paragraph 46: NHS Act 2006 new section 134(4A) – Power conferred on Secretary of State to make regulations about remuneration for services under pilot schemes

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

339. New sub-section 134(4A) of the NHS Act 2006 enables the Secretary of State to make provision in regulations about the remuneration that is to be paid to persons who provide services under a pilot scheme, including provision about the determination of the remuneration and who is liable to pay. The latter could include imposition of liability to make payments directly on the Secretary of State.

Justification for taking the power

340. The Bill makes ICBs the sole commissioners of local pharmaceutical services, as opposed to NHSE or the Secretary of State. In order to support consistency in relation to how the remuneration arrangements and funding flows will operate across pharmaceutical and local pharmaceutical services, new section 134(4A) will enable the Secretary of State to make provision in regulations about Local Pharmaceutical Services pilot scheme remuneration (and new paragraph 3(3)(da) of Schedule 12 allows the Secretary of State to do the same for permanent Local Pharmaceutical Services contracts). The provision can be modelled, if the Secretary of State choses to do so, on the provision that may be made in regulations under section 164 of the NHS Act 2006.

Justification for the procedure

341. The department considers that the negative procedure is appropriate. During the Bill's passage, Parliament will have the opportunity to consider the substance of the duties being placed on ICBs in relation to the provision of pharmaceutical services and any regulations made using these powers will seek to ensure that only appropriate assistance and support is offered. The negative procedure is therefore considered to strike the right balance between scrutiny and flexibility.

Paragraph 50: NHS Act 2006 revised section 140 – Power conferred on Secretary of State to make regulations for an integrated care board or the Secretary of State to make payments for preparatory work

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

342. Currently, the Secretary of State may make regulations for NHSE to provide funding for work connected to preparing proposals for a local pharmaceutical services pilot scheme or work done in preparing to deliver a pilot scheme. The Bill will amend section 140 of the NHS Act 2006 so that the regulations made by the Secretary of State under that section can make provision for the Secretary of State or ICB to provide this funding.

Justification for taking the power

343. The nature of different pilot schemes, and the cost of preparatory work related to each scheme will vary over time, therefore this power allows the Secretary of State to react to any such changes as appropriate.

Justification for the procedure

344. This does not confer new powers on the Secretary of State but retains the existing power. The regulations are currently subject to the negative procedure and the department considers that this remains appropriate in balancing scrutiny with flexibility.

Paragraph 67: NHS Act 2006 revised section 164 – Power conferred on Secretary of State to make regulations for the remuneration of pharmaceutical services

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

345. Currently, remuneration for pharmaceutical services must be determined by determining authorities. The Secretary of State and, when authorised by the Secretary of State, others such as NHSE can be determining authorities. Regulations under section 164 of the NHS Act 2006 may already make some provision about what is included in the determinations.

346. The Bill replaces the ability for the Secretary of State or NHSE to make determinations for the remuneration of pharmaceutical services directly under the NHS Act 2006 with an expanded regulation making power for the Secretary of State. Under the Bill, the Secretary of State must make regulations about the remuneration to be paid for pharmaceutical services. These regulations must include provision about determinations of the remuneration and who is liable to pay the remuneration.

Justification for taking the power

347. The current system is predicated on NHSE being at the heart of the arrangements for funding flows. Where liabilities for making payments will sit after its abolition – potentially either with the Secretary of State or with ICBs – and how the funding flows will operate has not yet been determined. The intention is to establish a flexible system so that the essential framework for responsibilities and liabilities will, going forward, be provided for by regulations. This will result in determinations being made under the regulations instead of under the NHS Act 2006 directly.

Justification for the procedure

348. The department considers that the negative procedure is appropriate due to the technical nature of the regulations.

349. At present, determinations can be made directly under the NHS Act 2006 but some aspects of what may be included in determinations are already covered by regulations. Requiring determinations to be made under regulations would allow the flexibility required to make clear where liability for different types of pharmaceutical services sits. There will also be more opportunity for Parliament to scrutinise the processes.

Paragraph 74: NHS Act 2006 revised schedule 12, paragraph 1(2ZA) – Power conferred on Secretary of State to prescribe who integrated care boards are responsible for

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

350. Currently, NHSE may establish Local Pharmaceutical Services schemes. The Bill will enable ICBs to establish Local Pharmaceutical Services schemes through consequential amendments to sub-paragraphs 1(1) and 1(2) of Schedule 12 to the NHS Act 2006. Amendments to sub-paragraph 1(2) specify that such pilot schemes will provide local pharmaceutical services to people for whom the ICB establishing the LPS scheme is responsible.

351. New paragraph 1(2ZA) is added to provide a clarification about who an ICB has responsibility for. These are people for whom ICBs have core responsibility, as specified in section 14Z31(2ZA)(a) but also any other people as may be prescribed (2ZA)(b) by means of regulations. New paragraph (2ZA)(b) therefore gives the Secretary of State an additional power to prescribe, in regulations, further categories of people for whom an ICB has responsibility.

Justification for taking the power

352. The power conferred on the Secretary of State in new paragraph (2ZA)(b) enables the Secretary of State to prescribe a further category of people for whom ICBs are responsible to ensure they receive local pharmaceutical services (usually very similar to the services provided under the national framework for pharmaceutical services, but there is more scope for local variation). This will help ensure people who do not live in the area of the ICB can access pharmaceutical services at or from pharmacies located in the ICB area. This aims to preserve freedom for people in England to choose which pharmacy to receive services from, including distance selling pharmacies who provide services nationally, or a pharmacy near a person's workplace rather than their home. Taking a power to do this by way of regulations enables there to be flexibility built into the system to respond to changing needs in the sector.

Justification for the procedure

353. The department consider that the negative procedure is appropriate. The affirmative procedure would not be appropriate as these regulations would not lead to significant policy changes but instead would be made to ensure the smooth running of, and allow for more flexibility in the provision of, pharmaceutical services within the framework already established under existing legislation. Equally the regulations may need to be amended to reflect necessary changes to who ICBs should be responsible for, and so the negative procedure strikes the right balance between scrutiny and flexibility. This approach is consistent with the approach taken under section 14Z31 (in respect of regulations making provision about persons who ICBs have responsibility for) and the regulation making powers under, for example, new sections 126(8A)(b) and 127(3A)(b).

Paragraph 74: NHS Act 2006 revised schedule 12, paragraph 3(3)(da) – Power conferred on Secretary of State to make regulations about remuneration for local pharmaceutical services

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

354. Currently, the Secretary of State may make regulations with respect to local pharmaceutical services. The Bill broadens these regulation making powers by enabling the Secretary of State to also make provisions about the remuneration to be paid for services delivered under a local pharmaceutical services scheme and who is liable to pay it.

Justification for taking the power

355. The Bill makes ICBs the sole commissioners of local pharmaceutical services, as opposed to NHSE or the Secretary of State. In order to support consistency in relation to how the remuneration arrangements and funding flows will operate across pharmaceutical and local pharmaceutical services, new section 134(4A) of the NHS Act 2006 will enable the Secretary of State to make provision in regulations about Local Pharmaceutical Services pilot scheme remuneration, and new paragraph 3(3)(da) of Schedule 12 allows the Secretary of State to do the same for permanent Local Pharmaceutical Services contracts, and in both cases the provision can be modelled if the Secretary of State choses to do so, on the provision that may be made in regulations under section 164 of the NHS Act 2006.

Justification for the procedure

356. The department considers that the negative procedure is appropriate. It is the procedure also for setting the framework for remuneration for LPS pilot schemes and for the regulations under section 164.

Paragraph 75: NHS Act 2006 revised schedule 12A paragraph 2 – Power conferred on Secretary of State to make apportionments to the ICBs for remuneration for pharmaceutical services
Power conferred on: Secretary of State
Power exercised by: Statutory Determination
Parliamentary procedure: None

Context and purpose

357. Currently, NHSE is liable for making payments of pharmaceutical remuneration and those payments can be apportioned to ICBs. In practice, most costs are allocated to the ICB of the prescriber. Amendments to schedule 12A paragraph 2(1) transfer the power to determine the elements of pharmaceutical remuneration that could be apportioned to ICBs from NHSE to the Secretary of State. Where such a determination is made, paragraph 2(4) places a duty on the Secretary of State to apportion the sums paid among all ICBs in a manner that the Secretary of state thinks is appropriate.

Justification for taking the power

358. As indicated in relation to the amendments to section 165 of the NHS Act 2006, it has not yet been determined where liability will sit for making payments of pharmaceutical remuneration. If that liability is conferred on the Secretary of State, it may nevertheless be appropriate for the costs to sit with ICBs, usually (under the current arrangements) with the ICBs of the prescribers. The changes will enable those arrangements to continue, without making the ICB liable instead to make the payments.

Justification for the procedure

359. The type of financial arrangements that can be determined under amended paragraph 2 are technical and detailed in nature. This level of detail would not usually be included in a statutory instrument or be subjected to parliamentary scrutiny.

Paragraph 89: NHS Act 2006 revised section 259 - Sale of medical practices
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative procedure

Context and Purpose

360. Section 259 of the NHS Act 2006 prohibits the sale of goodwill of the medical practice of specified persons. This includes persons who have, at any time, provided or performed primary medical services under specified contracts or arrangements.

361. The Bill already updates section 259 so references to arrangements under section 83(2) of the NHS Act 2006 refer to section 83 more generally. A further government amendment was needed because the definition of "relevant area" still referred to NHS England. Following NHS England's abolition, relevant primary medical services contracts and arrangements will be commissioned by Integrated Care Boards, so the provision must be updated to include a regulation making power in respect of ICBs, while retaining the regulation making power in respect of NHS England for legacy arrangements.

Justification for taking the power

362. It is necessary to amend section 259 to reflect the transfer of commissioning responsibility for primary medical services to ICBs following NHS England's abolition. Without this amendment, the existing regulation-making power would not reflect the commissioning arrangements for those services following the Health Bill changes.

363. Although it may be possible to rely on the transitional power in the Bill to deal with transitional cases, the better approach is to retain the existing provision for NHS England and add provision for ICBs. This provides clarity on the face of section 259 and avoids relying solely on secondary legislation to preserve the position for legacy arrangements.

364. This is consistent with the overall approach taken in section 259, which retains references to predecessor bodies where those references remain relevant on an ongoing basis. Section 259 applies to persons who have, at any time, provided or performed services under the specified contracts or arrangements. References to NHS England may therefore continue to be relevant in relation to contracts or arrangements entered into before its abolition.

365. Retaining the NHS England provision, alongside new provision for ICBs, will preserve the existing policy position while ensuring the provision operates effectively under the future commissioning model.

Justification for the procedure

366. Regulations made under section 259 are subject to the negative procedure already, as already provided for in the NHS Act 2006. Parliament has therefore previously approved the use of the negative procedure when conferring the other regulation making powers in section 259 on the Secretary of State, and this remains the appropriate procedure. The amendment does not create a new substantive policy power but updates the existing regulation-making provision so that it continues to operate in relation to both ICBs and NHS England, where relevant.

367. It is therefore appropriate for the existing parliamentary procedure to apply this new power for consistency with related regulation making powers in section 259. This is proportionate because the amendment reflects the transfer of commissioning functions to ICBs and maintains the ongoing relevance of NHS England for legacy contracts or arrangements.

Schedule 3: Constitution of NHS foundation trusts

Paragraph 15: NHS Act 2006 new Schedule 7, paragraph 5(2)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

368. Paragraph 5(2) of substitute Schedule 7 to the NHS Act 2006 reproduces but adds to the existing requirement set out in paragraph 16(2) of Schedule 7 to the NHS Act 2006 which requires the Board of an NHS Foundation Trust to have one executive director who is a medical practitioner or dentist, and another executive director who is a nurse or midwife. The addition enables the Secretary of State to make regulations to set out exceptions to this requirement. While having these roles at Board level is generally essential to patient safety and quality of care at the provider, they may not, depending on the services an individual trust or type of trust provides, be necessary in all cases. This power could be used, for example, to make an exception where trusts do not provide direct patient care or where they provide only patient transport services, enabling the Secretary of State to require the appointment of a more suitable healthcare professional(s) as an executive director in place of the existing prescribed roles.

Justification for taking the power

369. The requirement for NHS foundation trusts to have these types of executive director is set out on the face of the primary legislation for the sake of transparency and to demonstrate the commitment to clinical leadership on foundation trust boards. However, the Secretary of State needs to have the flexibility to make exceptions to this requirement where, for a particular type of foundation trust, a different type of healthcare professional in a clinical leadership role would be more appropriate and being able to set this out in regulations will enable the Secretary of State to respond to changing needs, and feedback from, the provider sector.

Justification for the procedure

370. This proposed procedure is in line with the procedure which applies to other regulation making powers relating to appointments under the substitute Schedule 7 to the NHS Act 2006. We consider that the negative procedure strikes the right balance between Parliamentary scrutiny and the need for the Secretary of State to have flexibility in making exceptions to the general requirement for executive membership of NHS foundation trust boards to respond to changing needs in the sector.

Paragraph 15: NHS Act 2006 new Schedule 7, paragraphs 5(4), 7, 8(4) and 9(1)
Power conferred on: Secretary of State
Power exercised by: Regulations

Parliamentary Procedure: Negative

Context and Purpose

371.The Bill amends the NHS Act 2006 to remove the requirement for NHS foundation trusts to have a council of governors and the council of governors' powers to appoint the chairs and other non-executive directors to their boards. The power to appoint chairs and non-executive directors is being conferred on the Secretary of State instead. The substitute Schedule 7 to the NHS Act 2006 also confers regulation making powers on the Secretary of State to make provision about the eligibility, and process, for appointments of NHS foundation trust directors (executive and non-executive) as follows:

- Paragraph 5(4) – the circumstances in which a person who is not an employee of the NHS foundation trust is, on appointment as a director, to be regarded as an executive rather than a non-executive director
- Paragraph 7 – further provision about eligibility for appointment as a director
- Paragraph 8(4) – circumstances in which powers related to the appointment, suspension or removal of non-executive directors and executive directors must be exercised
- Paragraph 9(1) – the tenure of office of non-executive directors

Justification for taking the power

372.Given that the Secretary of State is taking on a range of functions in relation to the appointments, and eligibility for appointment to, the boards of NHS foundation trusts, there is a need for balance between making provision as to the rules governing those appointments, and eligibility for them, on the face of the primary legislation, so that it is clear who has responsibility for the functions in future, with a need to be able to set certain additional rules flexibly to respond to changes in circumstances or needs in the NHS. The regulation making powers conferred on the Secretary of State under the substituted Schedule 7 mirror the regulation making powers conferred on the Secretary of State with regard to appointments in relation to NHS trusts.

Justification for the procedure

373.This procedure is in line with the procedure to which the equivalent regulation making powers conferred on the Secretary of State in relation to NHS trusts are subject. It is considered that the negative procedure strikes the right balance between Parliamentary scrutiny and the need for the detailed rules around appointments and eligibility for appointments being capable of being amended in reasonably quick order to respond to changes in circumstances or needs in the NHS.

Paragraph 15: NHS Act 2006 new Schedule 7, paragraphs 18(3), 18(4), 18(6) and 18(10)

Power conferred on: Secretary of State

Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

374. NHS foundation trusts are subject to accounting requirements to ensure their accounts have been prepared appropriately, and to rules as to the audit of those accounts. This power enables the Secretary of State to (a) direct an NHS foundation trust to prepare accounts for a specific period or periods (for example, for part of a financial year), (b) direct an NHS foundation trust that those accounts prepared for a specific period or periods must be audited in accordance with the requirements of the Local Audit and Accountability Act 2014, (c) direct an NHS foundation trust about the content and form of those accounts and the methods and principles the accounts must be prepared in accordance with and (d) direct an NHS foundation trust about the date by which it must send a copy of its accounts and the auditor's report on them to the Secretary of State.

Justification for taking the power

375. The Secretary of State has an existing power under current paragraph 24(1A) of Schedule 7 to the NHS Act 2006 to, with the approval of the Secretary of State, direct NHS foundation trusts as to the form in which their accounts must be kept.

376. The Bill substitutes a new paragraph 18 into Schedule 7 to the NHS Act 2006 to expand these powers of direction, as mentioned above. This reflects the approach taken in respect of the accounts of NHS trusts. The Secretary of State requires this delegated power as the detail of accounting methods and principles are more appropriately included in delegated legislation than on the face of the primary legislation. It also ensures that any updates to accounting methods and principles can be reflected in updated directions without the need for any amendment to primary legislation. In addition, the Secretary of State needs to be able to direct individual NHS foundation trusts about the period for which they should prepare accounts and have them audited in specific circumstances (for example, if a foundation trust is de-authorised half way through a financial year or otherwise ceases to be during a financial year by, for example, merging with another NHS trust or foundation trust) and by when they should send their accounts and auditors' report to the Secretary of State.

Justification for the procedure

377. Directions are considered to be the most appropriate form of delegated legislation here as their content will be technical, they need to be updated easily to reflect changes in accounting practices and principles, and there needs to be the flexibility to take different approaches to accounting periods and dates for submission of accounts for individual NHS foundation trusts, depending on differing circumstances. These types of delegated powers to

specify details around accounting principles, accounting periods and audit in NHS legislation are usually dealt with by means of directions for these reasons.

Paragraph 15: NHS Act 2006 new Schedule 7, paragraph 21(2)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

378.The Bill inserts a substitute Schedule 7 into the NHS Act 2006, which makes provision about the constitution of NHS foundation trusts. Paragraph 21(1) of that Schedule imposes a duty on NHS foundation trusts to publish certain documents including their register of directors and the register of interests of those directors. Paragraph 21(2) confers a power on the Secretary of State to make regulations to provide for exceptions to the duty to publish these registers.

Justification for taking the power

379.The Secretary of State requires a regulation making power so that provision can be made to reflect up to date considerations and circumstances around the need to protect any commercially or politically sensitive information or confidential personal information pertaining to the directors from publication whilst ensuring transparency is the overall policy objective. The types of exception and level of detail required are more suited to secondary rather than primary legislation.

Justification for the procedure

380.The negative procedure is considered appropriate to balance Parliamentary scrutiny and the need for the regulations to be made or amended quickly should new information come to light which affects what exceptions from publication might be required.

Paragraph 15: NHS Act 2006 new Schedule 7, paragraph 22
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

381.The Bill inserts a substitute Schedule 7 into the NHS Act 2006, which makes provision about the constitution of NHS foundation trusts. Paragraph 22 of that Schedule confers a power on the Secretary of State to make regulations to prescribe when an NHS foundation trust must hold a public meeting to present its audited annual accounts and its annual report, and

when it must otherwise hold a public meeting and what documents must be presented at this meeting.

Justification for taking the power

382. A regulation making power is needed here as the kind of details on timings of public meetings and documents to be presented at those meetings which they will set out are more appropriately placed in secondary legislation rather than on the face of the primary legislation, particularly as they may need to be amended regularly to reflect changing circumstances.

Justification for the procedure

383. An equivalent regulation making power in relation to the meetings and documents of NHS trusts is subject to the negative procedure, and it is considered that this strikes the right balance between appropriate Parliamentary scrutiny and the need for the regulations to be amended to respond to changing circumstances.

Schedule 4: NHS foundation trusts: Audit of accounts

Paragraph 12: Local Audit and Accountability Act 2014 new section 13(4)
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

384. If it appears that a health service body has failed to appoint an auditor the substituted power in section 13(4) of the Local Audit and Accountability Act 2014 permits the Secretary of State to direct a health service body to appoint an auditor named in the direction or appoint one on the health service body's behalf. The Local Audit and Accountability Act 2014 has always applied to other NHS bodies (being NHS trusts and ICBs); this amendment extends the arrangements to NHS foundation trusts and as such these amendments extend the powers so that they also apply in relation to NHS foundation trusts.

Justification for taking the power

385. The Bill 1) transfers NHSE's power under the Local Audit and Accountability Act 2014 regarding failure to appoint auditors to Secretary of State and 2) removes foundation trust governors (who have the legal power to appointment) and adds foundation trusts to the bodies coming under the Local Audit and Accountability Act 2014. Consequently, the Secretary of State, as they can with regard to ICBs and NHS Trusts, should be able to intervene when an NHS foundation trust (as a health service body under this legislation) has not appointed an auditor. This power enables the Secretary of State to ensure that the accounts are audited appropriately within a suitable timeframe.

Justification for the procedure

386. The department considers that no parliamentary procedure is required for the exercise of this power given that accounts and the audit of accounts are technical matters dealt with in the day to day running of a health service body, and such matters would usually fall to be dealt with by instruments which do not attract a parliamentary procedure. In addition, in the event of a failure to appoint an auditor, the Secretary of State would need to make a timely intervention to ensure that the appropriate audits are completed, so directions allow for such a speedy response.

Schedule 6: Trust special administration

Paragraph 2: NHS Act 2006 new section 65B(1)
Power conferred on: Secretary of State
Power exercised by: Order
Parliamentary Procedure: Statutory instrument which must be laid after being made

Context and Purpose

387. The Bill makes a range of amendments to the provisions of the NHS Act 2006 relating to the appointment of, functions of, and process to be followed by, trust special administrators to NHS foundation trusts and NHS trusts. The functions currently carried out by NHSE are to be conferred on the Secretary of State and there is a streamlining of the processes for NHS trusts and NHS foundation trusts to bring them into closer alignment. The substitute section 65B(1) provides the Secretary of State with a power, by order, to appoint a trust special administrator to an NHS trust or NHS foundation trust where the tests in subsection (2) are met. These vary for NHS trusts and NHS foundation trusts but, in both cases, there must be a serious failure by the trust to provide services that are of sufficient quality to be provided under the NHS Act 2006. The order is subject to consultation before being made and a report setting out the reasons for making the order must be laid before Parliament at the same time as the order itself is laid.

Justification for taking the power

388. The power to appoint a trust special administrator to an NHS trust or NHS foundation trust by means of order is necessary as it enables the Secretary of State to respond quickly and appropriately to deal with serious failures at such a trust and to ensure that the trust can continue to deliver services safely and efficiently for its patients. Previously, the power to appoint a trust special administrator to an NHS trust was conferred on NHSE (in current sections 65B and 65D of the NHS Act 2006) but with its proposed abolition, the order making power is conferred on the Secretary of State instead. It continues to be appropriate that these powers be exercised by means of secondary legislation so that quick and effective action can be taken to protect patients and the public.

Justification for the procedure

389. The current power to make an order appointing a trust special administrator to an NHS trust or NHS foundation trust is subject to the requirement that the order be laid after it is made (rather than before it is made). It is considered that this procedure continues to strike the appropriate balance between the need for Parliamentary scrutiny (noting the need for the Secretary of State to lay a report for the reasons for making the order alongside the statutory instrument itself) and the need for the Secretary of

State to take swift and efficient action to deal with serious failures at an NHS trust.

Paragraph 3: NHS Act 2006 new section 65F(2)
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and purpose

390. When a trust special administrator is appointed, they must publish a draft report recommending what action the Secretary of State must take in relation to the NHS trust. Under current section 65F the power to direct who the trust special administrator must consult when preparing this report is conferred on NHSE. With the abolition of NHSE, the Bill will confer the power to direct who the trust special administrator must consult with on the Secretary of State.

Justification for taking the power

391. The power to direct who the appointed trust special administrator must consult with when preparing a draft report is needed to ensure that all appropriate parties can give views on actions that should be taken when the Secretary of State needs to respond quickly and appropriately to deal with serious failures at an NHS trust. The identity of those appropriate parties will vary as between different trust special administrator appointments depending on the circumstances that have led to the appointment of the trust special administrator and the types of facilities at the NHS trust and the services the trust delivers. Previously, the power to direct who the trust special administrator consults was conferred on NHSE (in current section 65F(2) of the NHS Act 2006) but with its proposed abolition, that power of direction is conferred on the Secretary of State instead. It continues to be appropriate that these powers be exercised by means of direction so that they can reflect the individual circumstances surrounding a particular trust special administrator appointment to a particular NHS trust, and so quick and effective action can be taken to protect patients and the public.

Justification for the procedure

392. Directions that can be made by an instrument in writing without any parliamentary procedure are considered the most appropriate vehicle here so that the trust special administrator process can be progressed quickly, including the consultation on the draft report, to ensure the best outcome for patients and the public served by the NHS trust to which the trust special administrator is appointed.

Paragraph 5: NHS Act 2006 revised sections 65H (7)(c), (7)(d) and (9A)
Power conferred on: Secretary of State

Power exercised by: Directions
Parliamentary Procedure: None

Context and purpose

393.Under current subsection (7)(c) and (d) of section 65H of the NHS Act 2006, an appointed trust special administrator to an NHS trust must, during the consultation period on the draft report on the action it recommends is taken in relation to the NHS trust for which it is appointed, seek a written response from any member of Parliament or any other person that NHSE specifies in a direction. NHSE may also, under section 65H(9A), direct the trust special administrator to hold a meeting with any person. With the abolition of NHSE, the Bill confers these powers of direction on the Secretary of State instead.

Justification for taking the power

394.Providing the Secretary of State with a power to direct the trust special administrator on who to consult regarding their draft report ensures that all suitable parties can give views on actions that need to be taken when the Secretary of State needs to respond quickly and appropriately to deal with serious failures at an NHS trust. Previously, the power to give these directions was conferred on NHSE (in current section 65H of the 2006 Act) but with its proposed abolition, the power is conferred on the Secretary of State instead.

Justification for the procedure

395.The department considers that directions are the most appropriate vehicle here as the identity of those who the trust special administrator should consult will vary from case to case.

Paragraph 7: NHS Act 2006 revised section 65J(2)
Power conferred on: Secretary of State
Power exercised by: Order
Parliamentary Procedure: Statutory instrument which must be laid after being made

Context and purpose

396.Under current section 65J(2) of the NHS Act 2006, NHSE may where it believes it is not reasonable for the trust special administrator, in the specified period, to be able to carry out their duties to consult relevant parties and produce a draft and final report recommending actions the Secretary of State should take, make an order to extend the period. The Bill confers this order making power on the Secretary of State instead.

Justification for taking the power

397.Conferring this power to enable the Secretary of State to extend these periods by means of order is necessary as it ensures that a trust special

administrator would be able to be given extra time to carry out an appropriate investigation into serious failures at an NHS trust, come up with appropriate recommendations about action that should be taken and consult on those recommendations if there are good reasons why the time limits are overly restrictive in a particular case. Previously, the power to make the order was conferred on NHSE (in current section 65J (2)) but with its proposed abolition, the order making power is conferred on the Secretary of State instead. It continues to be appropriate that these powers be exercised by means of secondary legislation so that an individualised approach can be taken in particular trust special administrator appointments, to enable quick and effective action to be taken to protect patients and the public.

Justification for the procedure

398. The current power to make an order is subject to the requirement that the order be laid after it is made (rather than before it is made). The department considers that this procedure continues to strike the appropriate balance between the need for Parliamentary scrutiny and the need for the Secretary of State to take swift and efficient action to deal with serious failures at an NHS trust.

Paragraph 9: NHS Act 2006 new section 65L

Power conferred on: Secretary of State
Power exercised by: Order
Parliamentary Procedure: Statutory instrument which must be laid after being made

Context and purpose

399. Under current section 65L(2) of the NHS Act 2006, NHSE must make an order detailing when the appointment of a trust special administrator and the suspension of the NHS trust chairs and directors will come to an end (for an NHS trust). Additionally, under current section 65L(2B) NHSE must make the same order for NHS foundation trusts with the addition of detailing when the suspension of the governors will end. The functions currently carried out by NHSE are to be conferred on the Secretary of State, given NHSE's proposed abolition, and there is a streamlining of the processes for NHS trusts and NHS foundation trusts to bring them into closer alignment, as there will no longer be councils of governors for foundation trusts. Therefore, the requirement for the Secretary of State to make this order will be the same for NHS trusts and NHS foundation trusts.

Justification for taking the power

400. The requirement to set out when the appointment of a trust special administrator to an NHS trust or NHS foundation trust is to end by means of order is necessary as it ensures transparency when the Secretary of State has needed to respond quickly and appropriately to deal with serious failures at such a trust. Previously, the power to make the order was conferred on

NHSE (in current sections 65L (2) and (2B) of the 2006 Act) but with its proposed abolition, the order making power is conferred on the Secretary of State instead. It continues to be appropriate that these powers be exercised by means of secondary legislation so that an appropriate date for the end of the trust special administrator appointment and the suspension of the NHS trust's board can be set quickly and in response to the relevant circumstances at the trust, but with an appropriate level of Parliamentary scrutiny.

Justification for the procedure

401. The current power to make an order detailing when the appointment of a trust special administrator to an NHS trust or NHS foundation trust will end and the suspension of the chair and directors will end, is subject to the requirement that the order be laid after it is made (rather than before it is made). The department considers that this procedure continues to strike the appropriate balance between the need for Parliamentary scrutiny and the need for the Secretary of State to end the trust special administrator process as part of taking swift and efficient action to deal with serious failures at an NHS trust.

Paragraph 10: NHS Act 2006 revised section 65LA

Power conferred on: Secretary of State
Power exercised by: Order
Parliamentary Procedure: Statutory instrument which must be laid after being made

Context and purpose

402. Where the Secretary of State decides to dissolve an NHS trust under new section 65K(1) of the NHS Act 2006, they may make an order to dissolve the trust and transfer the property, liabilities and employees from the trust to the Secretary of State or another NHS body. Under current section 65K, this power is conferred on NHSE. With the abolition of NHSE, this power is being conferred on the Secretary of State.

Justification for taking the power

403. The power to dissolve an NHS trust by order at the end of the trust special administrator process enables the Secretary of State to respond quickly and appropriately to deal with serious failures at such a trust and to ensure that there is continuity of services delivered safely and efficiently for its patients. It continues to be appropriate that these powers be exercised by means of order so that quick and effective action can be taken to protect patients and the public at the end of the trust special administrator process.

Justification for the procedure

404. The current power to make an order dissolving an NHS trust or NHS foundation trust is subject to the requirement that the order be laid after it is

made (rather than before it is made). The department considers that this procedure continues to strike the appropriate balance between the need for Parliamentary scrutiny and the need for the Secretary of State to take swift and efficient action to deal with serious failures at an NHS trust.

Paragraph 11: NHS Act 2006 revised section 65M(2)
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and purpose

405.The Bill amends section 65M of the NHS Act 2006 to provide that if an appointed trust special administrator ceases to hold office during the administration period, the Secretary of State may appoint another trust special administrator. The actions of the previous trust special administrator continue to have effect unless the Secretary of State directs otherwise. Under current section 65M the power to direct in these circumstances is conferred on NHSE. With the abolition of NHSE, the power to direct whether the actions of the previous trust special administrator continue to have effect is conferred instead on the Secretary of State.

Justification for taking the power

406.The primary legislation provides that, where a trust special administrator is replaced, the actions of the previous trust special administrator continue to have effect, unless the Secretary of State provides otherwise in directions. The main proposition is therefore on the face of the primary legislation and will be the usual position. However, it is necessary to have the power to provide for an exception to this to deal with the particular circumstances of each trust special administrator process – for example, in a particular case it may be necessary for actions to be repeated such as where the Secretary of State suspects that the trust special administrator originally appointed may not have conducted the investigation appropriately. Previously, this power of direction was conferred on NHSE, but with its proposed abolition, it is conferred on the Secretary of State instead. It continues to be appropriate that these powers be exercised by means of direction so that the Secretary of State can respond quickly and take effective action to protect patients and the public, tailored to the particular trust special administrator appointment.

Justification for the procedure

407.Directions are considered to be the most appropriate vehicle here, given that the contents of the directions are likely to vary according to the circumstances of each NHS trust and trust special administrator appointment and will need to be made quickly if a trust special administrator is replaced.

Paragraph 12: NHS Act 2006 revised section 65N(1)
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and purpose

408.Currently NHSE is under a duty under section 65N(1) of the NHS Act 2006 to publish guidance to trust special administrators s about a range of specified matters. With the abolition of NHSE, the duty to publish this guidance will instead be conferred on the Secretary of State.

Justification for taking the power

409.Guidance setting out how a range of activities should be carried out by trust special administrators helps to provide further detail about how the trust special administrator process should work. Previously, the duty to publish this guidance was conferred on NHSE but with its proposed abolition, it is instead conferred on the Secretary of State.

Justification for the procedure

410.The guidance would not be subject to any parliamentary procedure. It continues to be appropriate that this information is set out in guidance as the level of detail required and the case studies and examples included in it would be inappropriate for the face of primary or secondary legislation and it can be updated quickly when new information comes to light.

Schedule 7: Pharmaceutical services: appeals etc

Paragraph 7: NHS Act 2006, revised section 158(9)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Negative

Context and purpose

411. The First-tier Tribunal is currently designated in the NHS Act to hear disputes relating to NHS commissioners' use of disqualification powers under Chapter 6. These powers concern fitness-related matters, including suitability, fraud, and efficiency of both existing and prospective NHS pharmaceutical service providers. In its role as disputes adjudicator, First-tier Tribunal also has the power under the Act to impose national disqualification of providers of pharmaceutical services.

412. The objective of the new power is to streamline the resolution process for disputes involving providers on the NHS pharmaceutical list and to reduce duplication and overlap within the current system. This new delegated power would enable the Secretary of State to specify in regulations the relevant appeals authority to arbitrate these disputes, including the transfer of the power to action national disqualification of providers from the NHS pharmaceutical lists in England.

Justification for taking the power

413. The new power conferred on the Secretary of State in new section 158(9) will allow the Secretary of State to ensure arbitration of these appeals is undertaken by the same appeal authority that arbitrates other disputes between pharmacy contractors and NHS commissioners. The name of the body may change over time, so it is not appropriate to designate in the NHS Act which body will take on this function.

Justification for the procedure

414. The department consider that the negative procedure is appropriate, this strikes the right balance between appropriate Parliamentary scrutiny and the need for the regulations to be amended to respond to changing circumstances.

Schedule 8: Health and Social Care Information Systems etc

Paragraph 16: Health and Social Care Act 2012, new section 265
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and Purpose

415. Section 265 of the Health and Social Care Act 2012 confers powers and imposes duties on NHSE to give advice and guidance to, respectively, certain persons (including health or social care bodies) on matters relating to the collection, analysis, publication or other dissemination of information and to the Secretary of State, or persons specified by the Secretary of State, on matters specified by the Secretary of State.

416. In consequence of the abolition of NHSE, paragraph 16 of Schedule 8 substitutes section 265 with a new provision which confers a power on the Secretary of State to issue guidance to health or social care bodies on matters relating to the processing of information insofar as relevant to the exercise of their functions in connection with the provision of health services or of adult social care in England. A health or social care body must have regard to the guidance.

Justification for taking the power

417. The power to issue guidance will enable the Secretary of State to guide health or social care bodies on matters relating to the processing of information insofar as relevant to the exercise of their functions, and to provide examples of best practice and establish key principles. It would not be appropriate to put this level of detail on the face of the Bill and doing so would limit flexibility to amend the guidance in the light of changing needs.

Justification for the procedure

418. The level of detail required in the guidance issued under this power and its non-controversial nature mean that a Parliamentary procedure is not required. This would be consistent with the current power to issue guidance under section 265.

Paragraph 19: Health and Social Care Act 2012, revised section 267
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

419. Section 267 of the Health and Social Care Act 2012 enables the Secretary of State, through regulations, to make provision for a scheme to accredit information service providers, namely organisations that act as information intermediaries. The regulations may provide for the accreditation scheme to be established and operated by NHSE or other persons specified by the Secretary of State in regulations.
420. In consequence of the abolition of NHSE, this provision amends section 267 to require regulations to provide for such schemes to be established and operated by the Secretary of State, or a public body designated by the Secretary of State in accordance with the regulations.
421. This provision also broadens the definition of an "information service provider" to cover public bodies (who are currently excluded from the definition) as well as any person who provides services involving the "processing" of information generally (rather than just the "collection, analysis, publication or other dissemination" of information).
422. Information intermediaries ("information service providers") take available information about NHS, public health and adult social care services and process that information to add value. Information intermediaries would enable NHS-derived data to be made available much more freely and in innovative ways that make sense to and can be easily used by people with an interest.
423. Subsections (3) and (4) of section 267 set out the scope of the regulation-making powers, in particular that they may require the operator to publish details of the scheme including the accreditation criteria and to provide for reviews of decisions. The operator may also be required by regulations to provide advice to applicants on how to meet the criteria and be permitted to charge a reasonable fee in respect of an application.
424. An accreditation scheme would be intended essentially to kite-mark information service providers that meet certain criteria in order to enable those seeking the services of such a provider to select one that has demonstrated that it meets the necessary quality standards.

Justification for taking the power

425. The procedures for the operation of an accreditation scheme would be technical and require more detail to describe than would usually be included in primary legislation.

Justification for the procedure

426. Regulations under this section will be subject to the negative procedure. The negative procedure is proportionate as it will provide Parliament with the opportunity to debate these matters, if necessary, whilst also recognising the limited, technical subject matter of the regulations.

Schedule 9: Transfer of HSSIB's functions to CQC

Paragraph 4: Health and Social Care Act 2008 new section 51B
Power conferred on: Secretary of State
Power exercised by: Direction
Parliamentary procedure: None

Context and purpose

189. The HSSIB publishes recommendations to facilitate the improvement of systems and practices in the provision of NHS services or other health care services in England. On the abolition of HSSIB, this role will be conferred on the CQC.
190. New section 51B of the Health and Social Care Act 2008 inserted by Schedule 9 confers a power on the Secretary of State to direct the CQC to investigate particular qualifying incidents, or qualifying incidents of a particular description. This direction may specify the date by which the CQC must publish its final report. This replicates the existing Secretary of State power to direct HSSIB in section 111(2) of the Health and Care Act 2022.

Justification for taking the power

191. This power will help identify risks to the safety of patients and address those risks, by giving the Secretary of State a referral mechanism by which investigations can be initiated, similar to the existing power in relation to HSSIB.
192. It is not possible to outline types of incident prospectively, or individual incidents, which should automatically be referred to the CQC for investigation and set these out in primary legislation. It is more appropriate for the Secretary of State to evaluate whether qualifying incidents which the CQC is not currently investigating, should be investigated.
193. The direction may provide for a person to exercise a discretion in dealing with any matter. There are circumstances in which allowing a person to exercise discretion would result in a more effective investigation, which would help improve the systems and practices in the provision of health care services in England.
194. The expectation is that a direction would only be used following discussions with the CQC.

Justification for the procedure

195. The department considers a Parliamentary procedure unnecessary in the use of this power.
196. It may be necessary for the Secretary of State to refer a qualifying incident to the CQC for investigation at short notice, and the time that would be taken by the scrutiny of these referrals may be detrimental to patient safety.
197. A relevant Secretary of State direction making power already exists in relation to HSSIB at section 111(2) of the Health and Care Act 2022 and the

Bill confers an equivalent power on the Secretary of State in relation to CQC when carrying out investigations.

Paragraph 4: Health and Social Care Act 2008 new section 51N
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary procedure: Affirmative

Context and purpose

198. Under new section 51M of the Health and Social Care Act 2008, CQC and connected individuals (such as a member of CQC, any of its committees, an investigator or someone who works for it) are prohibited from disclosing "protected materials" (information, documents or equipment held by CQC for the purposes of investigating and related to a qualifying incident, unless its content is available to the public) to anyone. New section 51N of the Health and Social Care Act 2008 provides a number of exceptions to this prohibition, including for disclosures required or authorised by regulations. Such regulations may be made by the Secretary of State to require or authorise the disclosure of protected materials. The prohibition on disclosure and the Secretary of State's power to introduce exceptions to it by regulations reflect the current provisions in sections 122 and 123 of the Health and Care Act 2022 with respect to HSSIB.

Justification for taking the power

199. Given the broad scope of the CQC's new investigation function, it is beneficial to allow some flexibility so the Secretary of State is able to amend circumstances under which protected materials may be disclosed in light of stakeholder proposals, should the need arise.

200. Within the regulations, the Secretary of State may provide for a person to exercise a discretion in dealing with any matter. There will be circumstances in which another person exercising their discretion would better preserve the integrity of the prohibition on disclosing protected materials. For example, if the Health and Safety Executive provides the CQC with advice to support an investigation, the Secretary of State could make regulations allowing for the disclosure of this advice, if the Health and Safety Executive believes it is in the public interest to do so. Here, the Health and Safety Executive would be better placed than the Secretary of State to determine whether it would be appropriate to disclose the protected material.

Justification for the procedure

201. In order for effective investigations to be conducted and for witnesses to feel comfortable to cooperate, they must feel that the materials and information they submit will remain confidential. Therefore, before additional circumstances where disclosure of protected material is permitted are stipulated, it must be properly considered whether this would impede the

CQC's ability to investigate qualifying incidents and encourage witnesses to cooperate. The affirmative procedure ensures that Parliament are able to scrutinise the proposed regulations in light of this need.

Paragraph 4: Health and Social Care Act 2008 new section 51Q
Power conferred on: CQC
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

202. New section 51Q of the Health and Social Care Act 2008 imposes a duty on CQC and other listed organisations to cooperate with each other when the CQC is investigating a qualifying incident under new section 51A of that Act and a listed organisation is investigating the same or a related incident. An equivalent duty is currently imposed on HSSIB under section 126 of the Health and Care Act 2022.

203. CQC must publish guidance about when a qualifying incident will be regarded as related to another incident for the purposes of the co-operation clause. A qualifying incident is an incident that occurs in England during the provision of health care services that has or may have implications for the safety of patients. If either an incident is being investigated by a listed person and deemed to relate to a qualifying incident which the CQC is investigating, or the CQC and a listed person are investigating the same incident, the person and the CQC will be under a duty to co-operate with each other regarding practical arrangements for co-ordinating those investigations.

Justification for taking the power

204. When the same incident is being investigated by the CQC and a listed person, the duty to co-operate will apply. The guidance will set out whether certain incidents are 'related' to a qualifying incident, and therefore whether the duty to co-operate applies in these situations. The CQC can undertake a wide variety of investigations, and therefore it would be difficult to prospectively outline how narrowly or broadly 'related to another incident' should be interpreted. If this is interpreted too broadly, it could result in the CQC and listed persons wasting resources for little to no benefit. If it is interpreted too narrowly, listed persons may not co-operate with the CQC and this could result in inefficiencies, such as a failure to appropriately share information. Setting out these details in guidance is the best option for ensuring better operational outcomes, and the CQC will be best placed to determine the content of the guidance.

Justification for the procedure

205. A Parliamentary procedure is considered unnecessary; it would be unusual for Parliament to scrutinise this type of guidance, and the department does not consider there is a need to depart from this position.

Paragraph 20: Health and Social Care Act 2008 new Schedule 2A, paragraph 8
Power conferred on: CQC
Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

206. Paragraph 8 of new Schedule 2A to the Health and Social Care Act 2008 requires the CQC to publish guidance on when protected material should be disclosed, the types of protected material it might be appropriate to disclose under various provisions of the Schedule and the processes which should be used when disclosing such protected material.

Justification for taking the power

207. The publication of guidance will help ensure that the CQC takes a consistent approach to disclosure in these circumstances and follows appropriate procedures. As creating conditions in which witnesses feel comfortable to disclose sensitive materials with an investigation is fundamental for the CQC to undertake effective investigations, it is important that protected material is only disclosed by the CQC when necessary. Unnecessary disclosure of protected material would weaken public trust in the function and may result in those involved in investigations being less willing to co-operate and share information. This must be balanced against the potential benefits of disclosure. For example, a disclosure could result in a conviction for an offence relating to investigations, which may deter others from obstructing an investigator. CQC will have the benefit of insight from the HSSIB, gained through their investigations, as well as operational experience. Therefore, CQC would be best placed to issue this guidance.

Justification for the procedure

208. A Parliamentary procedure is considered unnecessary given the operational nature of this guidance.

Schedule 12: Minor and consequential amendments

Paragraph 114: NHS Act 2006 revised Section 12ZB(4) and (6)
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and Purpose

427. Section 12ZB(1) of the NHS Act 2006 confers a regulation making power on the Secretary of State to make provision 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 other goods or services that are procured together with those health care services.

428. Section 12ZB(4) of the NHS Act 2006 currently obliges NHSE to publish guidance about compliance with those regulations and to obtain the approval of the Secretary of State before publishing the guidance (under section 12ZB(6)). Section 12ZB(5) requires relevant authorities to have regard to any published guidance. The amendments made to section 12ZB by this paragraph of Schedule 8 confers the duty to publish the guidance on the Secretary of State instead. The obligation to seek approval of that guidance is omitted.

Justification for taking the power

429. The duty to publish guidance is transferred from NHSE to the Secretary of State. Guidance remains the appropriate vehicle to set out the detail about compliance with the section 12ZB regulations (because the level of technical and operational detail required would be inappropriate for primary or secondary legislation).

Justification for the procedure

430. The guidance which the Secretary of State will publish under section 12ZB will be detailed and scenario based. As is usual with guidance of this kind, it is not subject to parliamentary procedure.

Paragraph 139: NHS Act 2006 new section 14Z60A(1)
Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary procedure: None

Context and purpose

189. The Health and Care Act 2022 inserted section 68A and Schedule 10A into the NHS Act 2006. Schedule 10A to the NHS Act 2006 introduced intervention powers enabling the Secretary of State

to issue a direction calling in the reconfiguration of NHS services (in England) that are proposed by ICBs or NHSE. For the purposes of these powers, a reconfiguration means a change in the arrangements made by an commissioning body for the provision of NHS services, where that change has an impact on either the manner in which a service is delivered to individuals (at the point when the service is received by users), or the range of health services available to individuals The Bill omits Schedule 10A from the NHS Act 2006, with new similar provisions inserted in sections 14Z60A to 14Z60C of the NHS Act 2006.

190. The effect of an NHS service reconfiguration being called in is that the Secretary of State has the power to make any decision in relation to the proposed reconfiguration that could have been made by the ICB or NHSE. This includes the power to decide whether a proposal should, or should not proceed, or whether it should proceed in a modified form.

191. Following the abolition of NHSE, some of the commissioning functions which NHSE previously held, will be conferred on the Secretary of State, whilst other commissioning functions will be conferred upon ICBs. In future, reconfigurations of NHS services where the Secretary of State is the commissioner will not be within the scope of the call in power. This is because if they were in scope of the call in power the Secretary of State would be calling in their own commissioning proposal.

192. Reconfiguration of NHS services commissioned by ICBs will remain in scope of the call-in power. New section 14Z60A(1) provides the power for the Secretary of State to give a direction to an ICB calling in any ICB proposal for the reconfiguration of NHS services.

Justification for taking the power

193. It remains important for the Secretary of State to continue to have the power to intervene in NHS reconfigurations proposed by ICBs. This needs to be an agile power which can be deployed at pace in response to proposals by an ICB which the Secretary of State considers has met the criteria for call in.

Justification for the procedure

194. These powers relate to detailed operational matters in relation to proposals to reconfigure NHS services by ICB's. Currently, the Secretary of State's power to call in reconfiguration proposals is dealt with by means of directions so that it can be flexible, responsive and used at pace in response to ICB proposals. Directions remain the appropriate vehicle for the exercise of this power, and it is usual practice for matters of this sort to be carried out through directions rather than regulations. Issuing of these directions requires no Parliamentary procedure. This is consistent with current direction making powers in the NHS Act 2006.

Paragraph 139: NHS Act 2006 new section 14Z60A(8)
Power conferred on: Secretary of State

Power exercised by: Guidance
Parliamentary procedure: None

Context and purpose

195. Schedule 10A of the NHS Act 2006 provides existing powers for the Secretary of State to 'call-in' proposals for the reconfiguration of NHS services and to intervene by giving directions to NHS bodies in respect of those proposals. Schedule 10A is being repealed. The intervention powers in respect of reconfigurations by ICBs will now be contained in new sections 14Z60A-C. There is a requirement for statutory guidance to be published by the Secretary of State under paragraph 7 of Schedule 10A to the NHS Act 2006. The guidance currently sets out the responsibilities of NHSE, ICBs, relevant NHS providers (NHS trusts and NHS foundation trusts) and the Secretary of State where a reconfiguration proposal is called in, and addresses matters such as; timetables for decisions, how representations can be made and the details of how a decision made under the call in power should be implemented. NHSE, ICBs, and NHS providers must have regard to the guidance. An equivalent provision to this will be inserted in new section 14Z60A(8) in relation to ICBs and NHS providers. Section 14Z60A(9) sets out the obligation on ICBs and providers to have regard to the statutory guidance.
196. Following the abolition of NHSE, the Secretary of State will hold some of the commissioning functions currently held by NHSE, while others will be moved to ICBs.
197. Where responsibility for commissioning a service has moved to the Secretary of State, such reconfiguration proposals will not be in scope of the call in power and as a result such proposals will also be out of scope of the guidance.

Justification for taking the power

198. It remains important for the Secretary of State to have the power to issue guidance in respect of the Secretary of State's power to call in reconfiguration proposals. It is necessary for the guidance to set out in detail how the Secretary of State proposes to use the call in power so that ICBs and NHS providers have clarity about what to expect when a reconfiguration is called in. it is also important for ICB's and NHS providers to have clarity on their obligations under section 14Z60A(7) in respect of providing information to the Secretary of State. The level of operational detail to be included in the guidance would be inappropriate for primary or secondary legislation.

Justification for the procedure

199. This power relates to detailed operational matters and it would be usual practice for matters of this sort to be set out in guidance.

200. The department's view is that it would not be usual or proportionate for there to be parliamentary scrutiny of this type of statutory guidance.

Paragraph 264: Health and Social Care Act 2012 revised section 83

Power conferred on: Secretary of State
Power exercised by: Directions
Parliamentary Procedure: None

Context and Purpose

201. Currently, under section 83 of the Health and Social Care Act 2012, the Secretary of State has the power to make regulations which exempt from the requirement to hold an NHS provider licence certain persons or descriptions of person or certain healthcare services. Exemptions may be granted subject to conditions and, if they are, such conditions may require any person providing a service pursuant to the exemption to comply with any direction given by NHSE about such matters as are specified in the exemption or are of a description so specified. This direction making power will be conferred on the Secretary of State rather than NHSE under this Bill.

Justification for taking the power

202. With the abolition of NHSE, the Secretary of State will continue to make regulations to provide for exemptions from the requirement to hold an NHS provider licence. However, as the Secretary of State will, in future, operate the provider licensing regime instead of NHSE, it is considered that the direction making power under section 83 should continue to be a dynamic way to provide specific instructions to classes of NHS providers whose exemption is subject to conditions to respond to evolving conditions in the provider sector.

Justification for the procedure

203. It is considered that, with exemption from holding a provider licence continuing to be governed by regulations, it is appropriate for directions to be used to detail conditions pursuant to the exemptions. .

Paragraph 267: Health and Social Care Act 2012 new section 86

Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

204. Currently the criteria for providers that must be met in order for them to be granted an NHS provider licence are set and published by NHSE and approved by the Secretary of State by means of an order. Substitute section 86 of the Health and Social Care Act 2012 imposes a duty on the Secretary

of State to make regulations to specify the criteria that must be met in order for a provider to be granted such a licence.

Justification for taking the power

205. With the abolition of NHSE, the intention is that the Secretary of State must set the criteria for the NHS provider licence by means of regulations. The criteria are very detailed and also need to be capable of being changed without the need for further primary legislation, so it is most appropriate that they are set out in secondary legislation.

Justification for the procedure

206. The negative resolution procedure is deemed appropriate here as it strikes the right balance between the need for Parliamentary scrutiny and the need for the criteria to be capable of being changed with relative ease to respond to changing circumstances. The licensing criteria are designed to set the operating parameters to support a practical licensing regime, e.g. setting a minimum financial threshold (in terms of NHS-funded care services turnover) to be licensed, as well as what types of providers should hold a licence. As such they are more operational in scope and it is appropriate that, should the health service require it, they can be amended relatively easily to reflect e.g. recommendations of Inquiries or changes in policy priorities whilst ensuring there is a proportionate Parliamentary role.

Paragraph 289: Health and Social Care Act 2012 revised section 108(1)
Power conferred on: Secretary of State
Power exercised by: Guidance
Parliamentary Procedure: None

Context and purpose

207. Under current section 108(1) of the Health and Social Care Act 2012, NHSE is required to publish guidance as to how it will use its enforcement powers under that Act. The enforcement guidance provides transparency and consistency for providers and commissioners on how NHSE will carry out investigations and ultimately use its enforcement powers to ensure that breaches of the NHS provider licence or other statutory duties are addressed. With the abolition of NHSE, the Bill will confer this duty on the Secretary of State.

Justification for taking the power

208. Providers and commissioners need more detail on how the powers of enforcement that will be conferred on the Secretary of State under sections 105 and 106 of, and Schedule 11 to, the Health and Social Care Act 2012 will be exercised than could be appropriately placed on the face of the Bill. The guidance will provide all parties with a level of transparency about how enforcement will operate in practice.

Justification for the procedure

209. The department considers a parliamentary procedure unnecessary because the level of detail and technical information on how the Secretary of State will use enforcement powers is too high to be appropriate for the face of primary or secondary legislation. The clause also places a duty on the Secretary of State to consult on this guidance prior to publication, allowing input from the sector. Guidance is the current mechanism by which this information is communicated, and the Secretary of State will be required to have regard to this guidance when using the enforcement powers under the Act.

Paragraph 307: Health and Social Care Act 2012 new section 139(1B)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

210. This paragraph inserts a new subsection into section 139 of the Health and Social Care Act 2012 to confer on the Secretary of State a power to make regulations to set a cap on the overall amount that can be raised from levies imposed on providers to establish a fund for the purpose of providing financial assistance under Chapter 6 of that Act. Chapter 6 is yet to be commenced.

Justification for taking the power

211. The cap may need to vary to take into account changes in the provider sector and the financial climate and so enabling it to be set by means of regulations rather than on the face of the Bill acknowledges this need.

Justification for the procedure

212. The negative resolution procedure is deemed to be the most appropriate procedure for these regulations, bearing in mind the need for Parliamentary scrutiny balanced against the need for the cap to be updated regularly.

Paragraph 330: Care Act 2014 amended section 12(10)
Power conferred on: Secretary of State
Power exercised by: Regulations
Parliamentary Procedure: Negative

Context and Purpose

213. The Care Act 2014 is the framework under which local authorities provide, in general terms, adult social care. Under sections 9 and 10 local authorities must assess those who appear to be in need of care and support and carers who appear to be in need of support. Section 12 makes further provision in relation to assessments conducted under sections 9 and 10 of the Act.

214. Section 12(1) requires the Secretary of State to make regulations about assessments which may (at (e)): *'specify circumstances in which the local authority must refer the adult concerned for an assessment of eligibility for NHS continuing healthcare.'*
215. The purpose of section 12(1) being that provision of NHS health care may need to be considered and a local authority carrying out an assessment under the Care Act 2014 should refer a person to the relevant body for that consideration in particular circumstances. The Care and Support (Assessment) Regulations 2014 (the 2014 Regulations) have been made under that under section 12 and regulation 7 determines the appropriate circumstances.
216. Section 12 and the 2014 Regulations rely on a definition of NHS continuing healthcare (CHC). It is defined in section 12, subsection (10): *"NHS continuing health care" is to be construed in accordance with standing rules under section 6E of the National Health Service Act 2006.*
217. The "standing rules" referred to in the section 12(10) of the Care Act are the *National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012* (the 2012 Regulations) (SI 2012/2996). The 2012 Regulations are made via the negative procedure under Section 6E of the 2006 NHS Act. The legislative framework for CHC is set out Part 6 of the 2012 Regulations.
218. Section 6E of the 2006 NHS Act is being revoked by clause 16 of the Health Bill. As such the 2012 Regulations will also be revoked and the definitions in section 12(10) of the Care Act will no longer work. Amended Section 12(10) of the Care Act 2014 creates a power to make regulations which set out a new definition of "NHS continuing healthcare" which will only be known when relevant provisions of the 2012 Regulations have been replaced.
219. Additionally, that same definition of CHC as is currently in section 12(10) of the Care Act 2014 (see para 4 above) is in two further statutory provisions; section 52 of the Care Act 2014 and paragraph 8 of Schedule AA1 to the Mental Capacity Act 2005 (MCA).
220. Section 52 of the Care Act 2014 deals with local authorities' duties under sections 48(2), 50(3) and 51(3) of that Act, which are, broadly, duties that apply in the event of a social care provider failure. Specifically, for an adult whose case comes within section 48 (a temporary duty on a local authority) and who is receiving CHC, section 52(9) makes the Integrated Care Board (ICB) providing that CHC a relevant partner in meeting those obligations. The definition of CHC in section 52(10) of the Care Act 2014 applies to section 52(9).
221. As to the MCA provisions, Schedule AA1 to the MCA was introduced by the Mental Capacity (Amendment) Act 2019. Those provisions, which are not yet in force, create, broadly, a new administrative scheme for the authorisation of arrangements enabling care or treatment of a person who lacks capacity to consent to the arrangements, which give rise to a deprivation of that person's liberty. Under Schedule AA1, a responsible body (defined in paragraph 6) is able to authorise such arrangements.
222. Paragraph 6 identifies a responsible body for a particular individual and under paragraph 6(1)(d)(i), where the arrangements are being carried out

through CHC (but not mainly in a hospital), the responsible body in England is the relevant ICB. (In Wales, where the arrangements are carried out mainly through the provision of an equivalent to CHC, the responsible body is the Local Health Board.) CHC is defined in paragraph 8 of Schedule AA1 to the MCA.

223. Once regulations are made in the exercise of the new power in section 12(10) of the Care Act 2014, the definitions will automatically be incorporated into section 52 of the Care Act 2014 and paragraph 8 of Schedule AA1 to the MCA.

Justification for taking the power

224. As Part 6 of the 2012 Regulations are intended to be revoked and the provisions will be replaced under powers in the Health Bill, there is presently no certain way of identifying the replacement. Therefore, there needs to be a mechanism by which the definition can be introduced into the Care Act and the MCA once that replacement process has been completed.

225. This new power in section 12(10) of the Care Act 2014 creates that mechanism.

226. Additionally, that mechanism will apply to section 52 of the Care Act 2014 and to paragraph 8 of Schedule AA1 to the MCA by amendments to each that tie the definitions of CHC in those provisions to the amended s.12(10).

227. Therefore, when those regulations under s.12(10) of the Care Act 2014 are made, each statutory provision will have the definition it requires.

Justification for the procedure

228. This delegated power will be subject to the negative parliamentary procedure. That allows Parliamentary scrutiny of regulations that incorporate the new definition of CHC.

229. The department considers that the negative procedure is appropriate. The legislative framework for CHC is currently set out in the 2012 Regulations, this includes the current definition. As set out in paragraph 6 those regulations are being revoked as a consequence of the revocation of section 6E of the NHS Act 2006 (clause 16 of the Bill) and the department's intention is the legislative framework will be replicated in directions made under new section 14Z61 (on eligibility and assessment), regulations made under new section 14Z45D (on appeals) and regulations made under section 12(10) of the Care Act (on the definition). The department's intention is to combine regulations made under sections 14Z45D and 12(10) into a single instrument.

230. There is therefore precedent for the definition of CHC being set out via the negative procedure and this continues to be the appropriate level of parliamentary scrutiny. It would be inconsistent for all the CHC provisions to made via negative regulations and directions save for the definition.

Department of Health and Social Care
September 2026

Annex A: Minor Amendments to delegated powers

Clause	Purpose of power
Clause 12(5): Commissioning functions: responsibility (amended section 4 of the NHS Act 2006)	Section 4 of the NHS Act 2006 is amended by Clause 12(5) to transfer the duty to arrange for the provision of high security psychiatric services from NHSE to the Secretary of State. Under the new provisions, Secretary of State can continue to direct a person who provides high security psychiatric services about the provision by that person of those services. The Clause adds that a direction may be given to a person other than a public authority if the Secretary of State is satisfied that the person would be required to comply with the direction by virtue of a condition of the person's licence. The Clause omits provision for the Secretary of State to direct NHSE.
Clause 23: Joint planning by Integrated Care Boards and their partners- annual report	Currently, under section 14Z58 of the NHS Act 2006, NHSE can direct ICBs on the form, content, and timing of their annual reports. The Bill transfers that same direction-making power to the Secretary of State, without materially changing the scope or nature of the power.
Clause 28: Special Health Authorities: establishment and exercise of functions	Section 28 of the NHS Act 2006 provides that the Secretary of State may, by order, establish an SpHA to exercise any functions which may be conferred on it by, or under, the NHS Act 2006. The Bill will expand this power to enable the Secretary of State to, by order, establish an SpHA to exercise functions under any enactment. The order making power is to continue to be exercised by the Secretary of State and to be subject to the same process and procedure.
Clause 28: Special Health Authorities: establishment and exercise of functions	Section 29 of the NHS Act 2006 sets out that Secretary of State regulations may provide for any functions which are exercisable by an SpHA under section 7 of the NHS Act 2006 to be exercised

	jointly with another SpHA, by another SpHA or by a committee, sub-committee or officer of the SpHA. This will be amended so that it applies to all functions exercisable by an SpHA, not just those conferred by means of directions under section 7 of the NHS Act 2006. The power to make the regulations remains with the Secretary of State and the regulations remain subject to the same process and procedure.
Clause 29: Special Health Authorities: staff transfers etc	Clause 29 amends paragraph 3 of Schedule 6 to the NHS Act 2006. Paragraph 3 deals with staff at SpHAs. Regulation making powers are set out in paragraph 3(8), and direction making powers in paragraph 3(12): No change is being made to who may exercise these powers, only the bodies they can be exercised in respect of. Changes are made to paragraph 3(8) which currently gives a power for regulations to provide: (a) for the transfer of officers from one SpHA to another, or to NHSE, and (b) for arrangements under which the services of an officer of a SpHA are placed at the disposal of another, NHSE or a local authority. The amendments will remove references to NHSE – in (a), it would be replaced with a reference to an ICB, and, in (b), it would be replaced with a reference to both an ICB and the Secretary of State. Amendments are also made to paragraph 3(12)(a) which currently allows for directions to be given by the Secretary of State to a SpHA to place the services of any of its officers at the disposal of another SpHA or of NHSE. Amendments will replace the reference to NHSE with a reference to both an ICB and the Secretary of State.

Clause 29: Special Health Authorities: staff transfers etc	Clause 29 amends paragraph 13 of Schedule 6 to the NHS Act 2006, which confers a regulation making power on the Secretary of State. No change is being made to the person who is to exercise this power, only to the bodies this power can be exercised in respect of. Paragraph 13 currently enables the Secretary of State to make regulations in relation to the recording of information by a SpHA and the furnishing of information by a SpHA to the Secretary of State, another SpHA or NHSE. The amendment to this paragraph will replace the reference to NHSE with a reference to an ICB.
Clause 36: Conversion of failing NHS foundation trust into NHS trust, subsection (6)(b).	Clause 36 subsection (6)(b) substitutes new paragraphs for paragraphs 5(1) and (2) of Schedule 4 to the NHS Act 2006 to reflect the position that, as a result of the introduction of a de-authorisation process for NHS foundation trusts in this Bill, an NHS trust may be established both under section 25 and new section 57B of the NHS Act 2006. This subsection amends the provisions which set out what an order made by the Secretary of State establishing an NHS trust must contain to reflect this.
Clause 40: Joint working and delegation arrangements, subsection (5)	New section 65Z7(1) provides that the Secretary of State may publish guidance for relevant bodies about the exercise of those bodies' powers under section 65Z5 (joint working and delegation arrangements) and section 65Z6 (formation of joint committees and pooled funds). The Secretary of State takes this power on from NHSE following its abolition.
Clause 46: Schemes for meeting liabilities	Section 71 of the NHS Act 2006 confers a power on the Secretary of State to make regulations to establish a scheme, with HMT consent, to meet expenses of specified bodies or other persons (as set out in

	section 71(2)) arising from any loss of or damage to property, and liabilities to third parties for loss, damage or injury arising out of the carrying out of their functions. The Bill will change the recipients of the scheme, so that it includes companies formed under section 223 other than those formed by an ICB by virtue of section 223A, and it will remove mentions of NHSE. The Secretary of State will retain the regulation making power.
Clause 48: Integrated care boards' funding and financial responsibilities	Section 223GC of the NHS Act 2006 requires ICBs to ensure that expenditure incurred in a financial year does not exceed the sums received by it in that financial year. It provides NHSE with a power of direction to specify expenditure or sums that are, or are not, toto be treated as incurred or received by an ICB in a particular financial year. The Bill confers this power of direction on the Secretary of State instead, so that the Secretary of State can direct ICBs as to what counts as expenditure and income within a particular financial year. This is a simple consequential amendment where the power is being transferred from NHSE to the Secretary of State.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 2 New section 82A of NHS Act 2006 - regulations to prescribe certain services as primary medical services	Section 83 of the NHS Act 2006 currently places a duty on NHSE to exercise its powers to secure the provision of primary medical services throughout England. The Bill inserts new section 82B, which places a duty on ICBs to exercise their powers in a way that secures the provision of these primary medical services for the people they will have responsibility for. Currently, under section 83(5), the Secretary of State has a regulation making power to prescribe services as "primary medical services" for the purposes of the NHS Act 2006, which informs the above

	mentioned duties. New section 82A, inserted by the Bill, reproduces this regulation making power – it will continue to be exercised by the Secretary of State and there are no changes to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 2 Section 82B of the NHS Act 2006 - ability to prescribe other persons that an ICB has responsibility for in relation to primary medical services	The Bill inserts new section 82B of the NHS Act 2006 (replicating an existing (uncommenced) power in paragraph 3 of Schedule 3 to the Health and Care Act 2022, which is to be omitted in this Bill, see paragraph 99 of Schedule 1) This places a duty on ICBs to secure the provision of primary medical services for persons for whom they have core responsibility and provides the Secretary of State with a power to make regulations to specify other persons whom an ICB will have responsibility for in respect of the commissioning primary medical services, in addition to persons for whom an ICB has core responsibility for by virtue of section 14Z31 of the NHS Act 2006. The Bill does not make any changes to this delegated power.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 2 Section 83A of the NHS Act 2006 - power to prescribe information in relation to primary medical services that ICBs must publish	Section 83(3) of the NHS Act 2006 currently places a duty on NHSE to publish such information as may be prescribed, by regulations made by the Secretary of State, in relation to primary medical services. The Bill, in new section 83A of the NHS Act 2006, reproduces this power to place the duty to publish such prescribed information on ICBs, as commissioners of primary medical services. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 4	Section 86 of the NHS Act 2006 currently enables the Secretary of State to make regulations in relation to persons eligible to enter into general medical services (GMS) contracts with NHSE.

Section 86 of the NHS Act 2006 - prescribe conditions in relation to persons eligible to enter into GMS contracts.	The Bill amends this power to reflect that GMS contracts will be entered into with ICBs, rather than NHSE. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 5 Section 87 of the NHS Act 2006 - Secretary of State direct about payments under GMS contracts	Section 87 of the NHS Act 2006 currently enables the Secretary of State to direct NHSE as to the payments made under GMS contracts. The Bill amends this power of direction of the Secretary of State so that it enables them to direct ICBs, instead of NHSE, as commissioners of GMS contracts. This power of direction remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1 paragraph 6 Section 89 of the NHS Act 2006 - regulations may describe terms that must be included in GMS contracts	Section 89 of the NHS Act 2006 currently gives the Secretary of State the power to make regulations prescribing terms that must be included in all GMS contracts between NHSE and GMS contract holders. The Bill amends this power of the Secretary of State, to reflect that ICBs will enter into GMS contracts with the GMS contractors. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 10 Section 94 of the NHS Act 2006 - regulations about provision of services under a s92 arrangements	Section 94 of the NHS Act 2006 provides the Secretary of State with the regulation making power that sets the mandatory terms of section 92 arrangements. Section 92 agreements must be made in accordance with regulations made under section 94. The Bill will amend this power of the Secretary of State, to reflect that ICBs, as commissioners of primary medical services, will enter into section 92 arrangements. The regulation making power remains with

	the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 12 Section 97 of the NHS Act 2006 - regulations requiring an ICB to consult a Local Medical Committee	Section 97(6) of the NHS Act 2006 currently provides the Secretary of State with a regulation making power that may require NHSE to consult with a Local Medical Committee, when exercising their functions in relation to primary care service. The Bill will amend this power of the Secretary of State to reflect that the regulations may require ICBs to consult with Local Medical Committees. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 14 Section 98C of the NHS Act 2006 - regulations to prescribe certain services as primary dental services	Section 99(1) of the NHS Act 2006 currently places a duty on NHSE to exercise its powers to secure the provision of primary dental services throughout England. New section 99 will place a duty on ICBs to exercise their powers in a way that secures the provision of these primary dental services within their area, to such extent as they consider necessary to meet the reasonable requirements of people seeking to obtain those services there. Currently, under section 99(5), the Secretary of State has a regulation making power to prescribe services as “primary dental services” for the purposes of the NHS Act 2006, which informs the above mentioned duties. New section 98C, inserted by the Bill, reproduces this regulation making power – it will continue to be exercised by the Secretary of State and there are no changes to its scope or nature.

Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 14 Section 99B of the NHS Act 2006 - power to prescribe information in relation to primary dental services that ICBs must publish	Section 99(3) of the NHS Act 2006 currently places a duty on NHSE to publish information as may be prescribed, by regulations made by the Secretary of State, in relation to primary dental services. The Bill, in new section 99B of the NHS Act 2006, reproduces this power to place the duty to publish prescribe information on ICBs, as commissioners of primary dental services. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 16 Section 102 of the NHS Act 2006 - prescribe conditions on entering into GDS contracts	Section 102 of the NHS Act 2006 enables the Secretary of State to make regulations that prescribe conditions in relation to persons eligible to enter into general dental services (GDS) contracts with NHSE. The Bill amends this power of the Secretary of State, to reflect the position that ICBs will enter into GDS contracts. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on Integrated Care Boards etc Part 1, paragraph 17 Section 103 of the NHS Act 2006 - Secretary of State direct about payments under GDS contracts	Section 103 of the NHS Act 2006 currently enables the Secretary of State to direct NHSE as to the payments made under GDS contracts. The Bill amends this power of direction of the Secretary of State so that it enables them, to direct ICBs, instead of NHSE, as commissioners of GDS Contracts. This power of direction remains with the Secretary of State and there is no other change to its scope or nature.

Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 18 Section 104 of the NHS Act 2006 - regulations may prescribe terms that must be included GDS contracts	Section 104 of the NHS Act 2006 currently enables the Secretary of State to make regulations prescribing terms to be included in all GDS contracts between NHSE and GDS contractors. The Bill will amend this power of the Secretary of State, to reflect that ICBs will enter into GDS contracts with GDS contractors. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 21 Section 108 of the NHS Act 2006 – regulations may prescribe conditions in relation to persons eligible to enter into agreements under section 107	Section 108(1) of the NHS Act 2006 currently gives the Secretary of State the power to prescribe conditions in relation to persons eligible to enter into agreements under section 107 for the provision of primary dental service (this includes Personal Dental Services Agreements). The Bill will amend this power of the Secretary of State, to reflect that ICBs will enter into section 107 arrangements. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 22 Section 109 of the NHS Act 2006 - regulations about provision of services under a section 107 arrangements	Section 109 of the NHS Act 2006 currently gives the Secretary of State a regulation making power that sets the mandatory terms of section 107 arrangements. Section 107 agreements must be made in accordance with regulations made under section 109. The Bill amends this power of the Secretary of State, to reflect that ICBs, as commissioners of primary dental services, will enter into section 107 arrangements. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 24	Section 113(6) of the NHS Act 2006 currently provides the Secretary of State with a regulation making power to require NHSE to consult with a

Section 113 of the NHS Act 2006 - regulations requiring an ICB to consult a Local Dental Committee	Local Dental Committee when exercising their functions in relation to primary dental services. The Bill will amend this power so that regulations can require ICBs to consult with Local Dental Committees. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 26 Section 114B of the NHS Act 2006 - regulations to prescribe certain services as primary ophthalmic services	Section 115 of the NHS Act 2006 currently provides the Secretary of State with the regulation making power to define which services must or must not be regarded as primary ophthalmic services for the purposes of the Act. New section 114B, inserted by the Bill, reproduces this regulation making power – it will continue to be exercised by the Secretary of State and there are no changes to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 28 Section 115(1)(b) of the NHS Act 2006 - power to prescribe other primary ophthalmic services that each ICB must commission.	Section 115(1) of the NHS Act 2006 currently confers a duty on NHSE to commission primary ophthalmic services. Section 115(1)(b)of the NHS Act 2006 currently enables the Secretary of State to prescribe other primary ophthalmic services that NHSE must commission. New section 115(1) inserted by the Bill, reproduces this regulation making power, but the related commissioning duty is amended to reflect that ICBs will commission primary ophthalmic services. The regulation making power will continue to be exercised by the Secretary of State and there are no changes to its scope or nature.

Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 29 Section 116B of the NHS Act 2006 - power to prescribe information in relation to primary ophthalmic services that ICBs must publish	Section 115(5) of the NHS Act 2006 currently provides the Secretary of State with a regulation making power to prescribe what information NHSE must publish in relation to primary ophthalmic services. The Bill, in new section 116B of the NHS Act 2006, reproduces this power to place the duty to publish prescribed information on ICBs, as commissioners of primary ophthalmic services. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 31 Section 118 of the NHS Act 2006; Power to prescribe conditions and exceptions as to persons eligible to enter into GOS contracts	Section 118(1) of the NHS Act 2006 currently enables the Secretary of State to make regulations to set conditions or exceptions governing who may enter into general ophthalmic services (GOS) contracts with NHSE. The Bill will amend this provision to recognise that ICBs will be commissioners of GOS contracts. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 32 Section 119 of the NHS Act 2006: Power to exclude contractors from entering into GOS contracts.	Section 119 of the NHS Act 2006 currently provides the Secretary of State with a regulation making power allowing NHSE or other prescribed bodies to apply to the First-Tier Tribunal for an order to disqualify individuals or organisations from entering into GOS contracts. The Bill will amend this power so that the Secretary of State can make regulations enabling ICBs to apply to the First-Tier Tribunal. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.

Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 33 Section 120 of the NHS Act 2006: Direction making power for payments under GOS contracts	Section 120 of the NHS Act 2006 enables the Secretary of State to direct NHSE as to payments payable under GOS contracts, such as for NHS sight tests provided by contractors to eligible groups. The Bill amends this power of direction to enable the Secretary of State to direct ICBs, instead of NHSE, as commissioners of GOS contracts. The power of direction will remain with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 34 Section 121 of the NHS Act 2006: Power to prescribe terms of GOS contracts	Section 121 of the NHS Act 2006 currently enables the Secretary of State to make regulations to specify mandatory terms for GOS contracts. The Bill amends this provision to reflect that the GOS contracts will be entered into by ICBs, as commissioner of GOS contracts. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 37 Section 125 of the NHS Act 2006 Power to make regulations in relation to Local Optical Committees	Section 125(7) currently enables the Secretary of State to make regulations to require NHSE, in the exercise of its functions relating to primary ophthalmic services, to consult Local Optical Committees. The Bill will amend this provision to enable the regulations to require that ICBs will consult with Local Optical Committees. The regulation making power remains with the Secretary of State and there is no other change to its scope or nature.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 39 Section 126 of NHS Act 2006 -arrangement for pharmaceutical services	The Secretary of State has an existing duty to make regulations concerning arrangements for the provision of sufficient drugs and medicines and listed appliances for persons whom NHSE is responsible for.

	The Bill replaces NHSE with ICB. This amendment transfers the obligation to make the above arrangements, in accordance with regulations made by the Secretary of State, to ICBs.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 40 Section 127 of NHS Act 2006 – arrangements for additional pharmaceutical services	The Secretary of State has existing powers to issue directions to NHSE requiring or authorising it to arrange additional pharmaceutical services. The Bill replaces NHSE with ICBs so that the Secretary of State can by direction either require ICBs to arrange additional pharmaceutical services or authorise ICBs to arrange the provision of such services.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 41 Section 128 of NHS Act 2006 – Terms and conditions, etc	The Secretary of State has existing powers to issue directions to NHSE under section 127. Section 128 sets out what these directions must and may include. The Bill makes changes to section 128 consequential on changes to section 127 so that provisions which may or must be included in directions made under section 127 direct ICBs instead of NHSE.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 42 Section 129 of NHS Act 2006 - Regulations as to pharmaceutical services	Currently, the Secretary of State must make regulations for arrangements to be made by NHSE for the market entry system for pharmacies, under which arrangements for the provision of sufficient drugs, medicines, and listed appliances are made. The Bill transfers the responsibility to make such arrangements to ICBs.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 43 Section 130 of the NHS Act 2006 – Regulations under section 129: appeals, etc	The NHS Act 2006 enables the Secretary of State to make regulations under section 129(6)(g) setting out additional grounds under which NHSE may refuse an application for inclusion in a pharmaceutical list. The Bill makes changes to section 130 consequential on the change to section 129 so that if the Secretary of State makes regulations under section 129(6)(g), such

	regulations will require ICBs, as opposed to NHSE, to provide a route of appeal when refusing an application.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 44 Section 131 of the NHS Act 2006 – power to charge	The Secretary of State has existing powers to issue directions requiring NHSE to charge fees in relation to applications to be added to a pharmaceutical list. The Bill replaces NHSE with ICB. This will enable the Secretary of State to direct ICBs to charge fees in relation to applications to be added to the pharmaceutical list.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 45 Section 132 of NHS Act 2006 - persons authorised to provide pharmaceutical services	The Secretary of State has an existing power to make regulations regarding provision of pharmaceutical services by medical practitioners or dentists. The Bill replaces NHSE with ICB as the responsibility for making such arrangements transfers to ICBs.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 47 Section 136 of the NHS Act 2006 – Designation of priority neighbourhoods or premises	The Secretary of State has an existing power to make regulations enabling NHSE to designate priority neighbourhoods or premises for pilot schemes. The Bill replaces NHSE with ICBs, so that regulations can be made which allow ICBs to designate priority neighbourhoods or premises in their areas.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 49 Section 138 of the NHS Act 2006 – Variation and termination of pilot schemes	The Secretary of State has an existing power to give directions authorising or requiring NHSE to vary or end pilot schemes. The Bill will make ICBs the sole commissioners of pilot schemes. This clause will give the Secretary of State the power to direct the ICB concerned to vary or end a pilot scheme.
Schedule 1 conferral of primary care functions on integrated care boards etc paragraph 55	Section 147B of the NHS Act 2006 provides that regulations under 147A may require a person on a pharmaceutical list to only employ a

Section 147B(2)(b) and (3).	person if they are listed on one of the lists set out in sub-section (2), including one prepared by NHS England. The references to NHS England are removed as NHS England will no longer be the body responsible for maintaining the relevant list.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 56 Section 148 of NHS Act 2006 – Conditional inclusion in pharmaceutical lists	Currently, the Secretary of State is able to provide in regulations that anyone included in a pharmaceutical list is subject to conditions determined by NHSE. The Bill will change this so that the regulations may provide that anyone on a pharmaceutical list is subject to conditions determined by the ICB in whose list the person is included.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 57 Section 150A of the NHS Act 2006 – Notices and penalties	The Secretary of State has an existing power to make regulations concerning notices and penalties for breaches of terms of service made with NHSE for the provision of pharmaceutical services. The Bill replaces NHSE with ICBs, so that regulations can be made concerning notices and penalties for breaches of terms of service.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 63 Section 158 of the NHS Act 2006 - Appeals	The Secretary of State has an existing power to make regulations for payments by NHSE to practitioners who are removed from a pharmaceutical list and whose appeals against this decision to the First-Tier Tribunal is successful. The Bill replaces NHSE with ICBs, so that regulations can be made for payments by ICBs to practitioners who are removed from that ICB's pharmaceutical list and whose appeal of this decision to the First-Tier Tribunal is successful.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 64	The Secretary of State has an existing power to make regulations to require NHSE to notify prescribed persons of decisions concerning disqualification from a pharmaceutical list.

Section 160 of the NHS Act 2006 – Notification of decisions	The Bill replaces NHSE with ICBs, so that regulations can require ICBs to notify prescribed persons of the decision an ICB makes concerning disqualification from the ICB's pharmaceutical list.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 65 Section 161 of the NHS Act 2006 – Withdrawal from lists	The Secretary of State has an existing power to make regulations specifying circumstances in which a practitioner who is being investigated by NHSE or has been removed from a pharmaceutical list by NHSE or suspended may not withdraw from a list in which he is included. The Bill will transfer responsibility to maintain pharmaceutical lists to ICBs. By replacing NHSE with ICB, the regulations can be made for circumstances where a practitioner is investigated by an ICB or removed from a list by an ICB.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 686 Section 162 of the NHS Act 2006 – Regulations about decisions under this Chapter	The Secretary of State has an existing power to make regulations for decisions concerning disqualification from a pharmaceutical list. The regulations must include provision to give practitioners the opportunity to put forward their case and to receive notice of a decision and rights of appeal. ICBs replace NHSE in the wider process, accordingly, NHSE is replaced with ICB in this section.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 70 Section 166 of the NHS Act 2006 – Indemnity cover	The Secretary of State has an existing power to make regulations to prescribe that persons on the pharmaceutical list hold approved indemnity cover. The Bill will transfer the responsibility to prepare and maintain a pharmaceutical list from NHSE to ICBs. Accordingly, NHSE is replaced with ICB in this section.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 71	The Secretary of State has an existing power to make regulations which may require NHSE to consult committees in the exercise of

Section 167 of the NHS Act 2006 – Local Pharmaceutical Committees	functions relating to pharmaceutical services or local pharmaceutical services. The Bill will transfer responsibility to recognise committees from NHSE to ICBs. Consequently, NHSE is replaced with ICB, so that regulations may require an ICB to consult committees recognised by the ICB on prescribed occasions.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 73 Schedule 11, paragraphs 2 to 5 and 7 and new paragraph 8 to the NHS Act 2006 – Pilot schemes, Preliminary steps to be taken	The Secretary of State has an existing power to direct NHSE to submit proposals for pilot schemes and the matters NHSE must have regard to in making any recommendations to the Secretary of State in these proposals. The Bill replaces NHSE with ICB, who will be the commissioners of pilot schemes once the Bill comes into effect.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 74 Schedule 12 to the NHS Act 2006 – local pharmaceutical services schemes	The Secretary of State has an existing power to make regulations with respect to local pharmaceutical services. These services can currently be established either by the Secretary of State or NHSE. The Bill transfers this function to ICBs and consequential amendments are made throughout Schedule 12 to reflect this change.
Schedule 1 Conferral of primary care functions on integrated care boards etc paragraph 74 Schedule 12 to the NHS Act 2006 - designation of neighbourhoods or premises	These powers restate existing powers in Schedule 12 for the Secretary of State to make regulations for the designation of priority neighbourhoods or premises. The requirements for such a designation may vary over time, so this power allows the Secretary of State to react to any such changes as appropriate.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 76	Section 176 of the NHS Act 2006 gives the Secretary of State the power to make regulations providing for the making and recovery of charges for relevant dental services. An amendment is made to the

Section 176 of the NHS Act 2006 - regulations providing for the making and recovery of charges for relevant dental services	regulation making power to reflect the position that ICBs will commission primary dental services instead of NHSE.
Schedule 1 Conferral of primary care functions on integrated care boards etc Part 1, paragraph 77 Section 180 of the NHS Act 2006 Power to provide for payments to be made to meet or contribute towards the costs of optical appliances and sight tests.	Section 180 of the NHS Act 2006 requires regulations to make provision for NHSE to make payments to meet or contribute towards the cost of optical appliances (for example, glasses, contact lenses) and sight tests, for eligible groups. It also enables NHSE to direct a SpHA or another, to be prescribed, to carry out their functions, that is, making payments. The Bill will transfer this duty to ICBs, following the abolition of NHSE, therefore the regulation making power has been updated to reflect the position that ICBs are taking on this role.
Schedule 2 - Patient Choice: undertakings by integrated care boards, paragraph 1 Inserting new Schedule 1C to the NHS Act 2006	New Schedule 1C to the NHS Act 2006 requires the Secretary of State to publish a procedure for entering into undertakings with an ICB, to republish that procedure when revised, and to publish any undertaking accepted from an ICB. These publication requirements ensure that the process for resolving failures is transparent, consistent, and publicly accessible. Equivalent duties are currently placed on NHSE in Schedule 1ZA to the NHS Act 2006. The Bill confers responsibility for these publication duties on the Secretary of State instead of NHSE without changing their substantive content or practical operation. The intent is to preserve transparency requirements while aligning responsibility with the Secretary of State's new oversight role following the wider transfer of functions.
Schedule 8, Health and social care information systems etc paragraph 20	Section 268 of the Health and Social Care Act 2012 enables regulations to confer functions on NHSE in connection with the establishment, maintenance and publication of a database of quality indicators in relation to the provision of health services and of adult

Section 268 of the Health and Social Care Act 2012: Database of quality indicators	social care in England. In consequence of the abolition of NHSE, paragraph 20 of Schedule 7 amends section 268 to enable regulations under that section to confer functions on the Secretary of State instead of NHSE in connection with the database. Section 268(2) sets out the scope of the regulation-making power including the assessment and approval processes for indicators proposed for inclusion in the database by persons directed by the Secretary of State and provision for advice and guidance to persons proposing indicators for inclusion in the database.
Schedule 8, Health and social care information systems etc paragraph 21 Section 269 of the Health and Social Care Act 2012: Power to confer functions in relation to identification of GPs	Section 269 of the Health and Social Care Act 2012 enables regulations to be made conferring functions on NHSE in connection with the verification of the identity of general medical practitioners for purposes connected with the health service in England. These are functions in relation to issuing Doctor Index Numbers to GPs. The process involves NHSE confirming the identity of a GP so that a unique number can be issued to individual GPs to enable them to prescribe. The system helps to ensure that only authorised GPs are able to issue prescriptions. The Bill amends section 269 to provide for regulations to confer such functions on the Secretary of State, instead of NHSE.

Schedule 9, Transfer of safety investigation functions to the Care Quality Commission- paragraph 13 Section 82 of the Health and Social Care Act 2008: failure by the Commission in discharge of functions	Section 82 of the Health and Social Care Act 2008 grants the Secretary of State the power to direct CQC to discharge its functions in a particular manner if it appears to Secretary of State that CQC is failing or has failed to discharge its functions or is failing or has failed to properly discharge its functions where that failure is significant. Section 82(2A) will be amended to ensure that the Secretary of State is not able to direct CQC to arrive at a particular outcome of an investigation it is carrying out into a qualifying incident under section 51A.
Schedule 9, Transfer of safety investigation functions to the Care Quality Commission, Part 2 – Other consequential amendments, paragraph 36 Section 253 of the NHS Act 2006: emergency powers	To remove the ability for the Secretary of State to give HSSIB directions under section 253 of the NHS Act 2006, given its abolition.
Schedule 10, Abolition of Healthwatch England, paragraphs 10 to 11 Section 83 and Section 84 Health and Social Care Act 2012: NHS provider licensing exemption regulations and exemption regulations: supplementary	Removal of references to NHSE and Healthwatch England, consequential on their abolition, from the requirement on the Secretary of State to notify NHSE and CQC including its Healthwatch England Committee when making regulations that exempt groups of providers from holding a provider licence.

Schedule 12, Minor and Consequential amendments paragraph 29 Section 117 Mental Health Act 1983 revised	Section 117 of the Mental Health Act 1983 places a duty on the NHS and local social services authorities to provide after-care to patients who have been detained in hospital for treatment under sections 3, 37, 45A, 47 or 48 of the 1983 Act, who then cease to be detained and leave hospital. The purpose of section 117 is to provide people with the right support that they need to live successfully and safely in the community. The responsibility for arranging and providing after-care services in England falls jointly on local social services authorities and ICBs pursuant to section 117(2). The Secretary of State has an existing power to make regulations to impose the duty on an ICB under section 117(2) of the 1983 Act on another ICB or NHSE. This provision amends that power to enable the relevant duty to be imposed on the Secretary of State their self.
Schedule 12, Minor and Consequential amendments paragraph 37 Section 2(9)(a) - Disabled Persons (Services, Consultation and Representation) Act 1986	Section 2(7) of the Disabled Persons (Services, Consultation and Representation) Act 1986 confers a power on the Secretary of State to make various orders. Section 2(9) defines the bodies to which such an order may apply for the purposes of that power. The Bill amends section 2(9) to remove NHSE from the definition of “health authority”, reflecting the abolition of NHSE. The order making power itself is unchanged.
Schedule 12, Minor and Consequential amendments, paragraph 82 Section 165 (3)b - Health and Social Care (Community Health and Standards) Act 2003	Section 165 of the Health and Social Care (Community Health and Standards) Act 2003 supports the operation of the NHS injury cost recovery scheme. That scheme applies where a person receives compensation for an injury and has received hospital treatment under an NHS arrangement. The purpose of section 165 is to enable regulations to be made to address practical legal issues that arise in applying the cost recovery scheme, so that the NHS can continue to recover the cost of treatment in cases where compensation is paid.

	Section 165 currently defines an NHS arrangement as including an arrangement between a hospital and NHSE. The Bill amends section 165 to remove the reference to NHSE, reflecting its abolition, and adding “the Secretary of State”, reflecting the transfer of NHSE’s functions to other bodies.
Schedule 12, Minor and Consequential amendments, paragraph 108 Section 7C of the NHS Act 2006 - power of direction: investigation functions	Secretary of State power of direction is amended to remove references to NHSE, and the definition in section 7C(9) of “investigation functions” is updated to reflect changes in the legislation. Consequential amendments are made to section 7D of the NHS Act 2006 in addition.
Schedule 12, Minor and Consequential amendments, paragraph 114 Section 12ZB NHS Act 2006 - procurement regulations	Section 12ZB(7) is amended to omit NHSE as a relevant authority which must follow the regulations and have regard to guidance issued.
Schedule 12, Minor and Consequential amendments Paragraph 125 Section 14Z25 NHS Act 2006 Duty to establish ICBs	Section 14Z25 of the NHS Act 2006 provides NHSE with a duty to establish, by order, ICBs. Section 14Z25 (5) states that an order establishing an ICB must provide for the constitution of the board, either by setting out the constitution or by making provision by reference to a published document where it is set out. Following the abolition of NHSE, Secretary of State will be given the power to establish new ICBs and vary ICB constitutions, instead of NHSE. Section 14Z25 (7) states that before varying or revoking an Establishment Order, NHSE must consult any ICB that it considers likely to be affected. Secretary of State will be under this duty in future.

Schedule 12, Minor and Consequential amendments Paragraph 135 Section 14Z51 NHS Act 2006 Guidance by NHSE	Section 14Z51 of the NHS Act 2006 requires NHSE to publish guidance for ICBs on the discharge of their functions. Section 14Z51(2) requires each ICB to have regard to guidance under this section. Following the abolition of NHSE, the Secretary of State will have a duty to issue guidance to ICBs on the discharge of their functions. Where guidance has already been issued by NHSE under section 14Z51 of the NHS Act 2006, ICBs will continue to have regard to it until it is replaced by guidance issued by the Secretary of State. This will ensure minimal disruption to the system during this period of wider change and will be achieved by consequential and transitional provisions in the Bill.
Schedule 12, Minor and Consequential amendments, paragraph 143 Subsection (3) of section 26A NHS Act 2006: Duty to have regard to wider effect of decisions	Under current section 26A of the NHS Act 2006, NHS trusts are required to have regard to NHSE guidance when discharging their duties in relation to the triple aim (improving the health of the population, improving quality of services and improving efficiency and sustainability of services). With the abolition of NHSE, the Bill will confer the function of issuing this guidance on the Secretary of State. This is an existing power to issue guidance currently conferred on NHSE which is, instead, being conferred on the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 144	Under current section 26B of the NHS Act 2006, NHS trusts are required to have regard to NHSE guidance when discharging their duties in relation to climate change. With the abolition of NHSE, the Bill

Subsection (2) of section 26B NHS Act 2006 Duties in relation to climate change etc	will confer the function of issuing this guidance on the Secretary of State. This is an existing power to issue guidance currently conferred on NHSE which is, instead, being conferred on the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 157 Subsection (3) of section 63A NHS Act 2006: Duty to have regard to wider effect of decisions	Under current section 63A of the NHS Act 2006, NHS foundation trusts are required to have regard to NHSE guidance when discharging their duties in relation to the triple aim (improving the health of the population, improving quality of services and improving efficiency and sustainability of services). With the abolition of NHSE, the Bill will confer the function of issuing this guidance on the Secretary of State. This is an existing power to issue guidance currently conferred on NHSE which is, instead, being conferred on the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 158 Subsection (2) of section 63B NHS Act 2006 Duties in relation to climate change etc	Under current section 63B of the NHS Act 2006, NHS foundation trusts are required to have regard to NHSE guidance when discharging their duties in relation to climate change. With the abolition of NHSE, the Bill will confer the function of issuing this guidance on the Secretary of State. This is an existing power to issue guidance currently conferred on NHSE which is, instead, being conferred on the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 169 Section 71 NHS Act 2006 - schemes for meeting losses and liabilities etc of certain health bodies	Section 71 of the NHS Act 2006 confers a power on the Secretary of State to make regulations to establish a scheme, with HMT consent, to meet expenses of specified bodies or other persons (as set out in 71(2)) arising from any loss of or damage to property, and liabilities to third parties for loss, damage or injury arising out of the carrying out of their functions. These minor amendments remove references to NHSE from the regulation making power.

Schedule 12, Minor and Consequential amendments, paragraph 172 Section 76 NHS Act 2006 - power of local authorities to make payments	Section 76 confers a power on local authorities to make payments to NHSE, an ICB or a Local Health Board towards expenses related to their prescribed functions, and the Secretary of State can prescribe conditions relating to these payments. The Bill replaces NHSE with the Secretary of State as a payment recipient in subsection 76(1). The Secretary of State will retain the power to give directions prescribing conditions relating to payments in section 76(3).
Schedule 12 Minor and consequential amendments, paragraph 175 Section 183 of NHS Act 2006 Power to make regulations in relation to the payment of travelling expenses	Section 183 of the NHS Act 2006 enables regulations to be made about the payment of travelling expenses to be made by the Secretary of State, NHSE, an ICB and NHS trust or an NHS foundation trust. The amendments to this section remove the references to NHSE.
Schedule 12 Minor and consequential amendments, paragraph 177 Section 185 of NHS Act 2006 Power to make regulations relating to charges for more expensive supplies	Section 185 of the NHS Act 2006 enables regulations to be made about the making and recovery of payments of more expensive supplies. These payments are made and recovered by the Secretary of State, NHSE, an ICB, a local authority, an NHS trust or an NHS foundation trust. The amendments to this section remove the references to NHSE.
Schedule 12, Minor and Consequential amendments, paragraph 180 Section 188 of the NHS Act 2006 - sums otherwise payable to those providing services	This section enables regulations to offset the charges payable by NHSE, an ICB or SpHA to the persons by whom services are provided. Subsection (1) sets out that the offsetting may apply to regulations made specifically under– a. section 172 (charges for drugs, medicines or appliances, or pharmaceutical service) b. section 179 (charges for optical appliances)

	c. section 185 (charges for more expensive supplies) or d. section 186 (charges for repairs and replacements in certain cases) Subsection (2) states that regulations may provide for the sums which would otherwise be payable by NHSE or an ICB or SpHA to the persons by whom the services are provided, to be reduced by the amount of the charged authorised by the regulations in respect of the services. There will be no change to the person who can exercise this power. The only change is that the reference to NHSE in section 188(2) is to be removed and reference to the Secretary of State is to be included. This ensures the Secretary of State can be involved in offsetting charges.
Schedule 12, Minor and Consequential amendments, paragraph 183 Section 222 NHS Act 2006 - power to raise money	Currently, under section 222 of the NHS Act 2006, NHS bodies (other than Local Health Boards) have the power to undertake fundraising activities, with NHSE able to issue directions to ICBs restricting certain activities within that function. The Bill transfers this direction-making power from NHSE to the Secretary of State, aligning it with similar powers the Secretary of State already holds in relation to other NHS bodies.
Schedule 12, Minor and Consequential, paragraph 187 Section 244 of the NHS Act 2006 - review and scrutiny of local authorities	Section 244 of the NHS Act 2006 relates to review and scrutiny by local authorities. Subsection (2) provides the Secretary of State with a regulation making power in relation to local authorities and their powers to review and scrutinise how health services are run in their specific area. Subsection (2ZA) additionally provides that the regulations may require an authority to refer matters to NHSE or the Secretary of State

	and, where it is NHSE, for NHSE to be subject to Secretary of State directions and capable of giving its own directions to ICBs. The powers under subsection (2ZA) are proposed to be removed, given: (a) NHSE abolition; (b) that the Secretary of State will have the general power of direction over ICBs in any event; and (c) that local authorities do not need a specific statutory power if they wish to refer a matter to the Secretary of State for consideration. The omission of subsections (2ZB) to (2ZC), and amendment to subsection (3), follow as a consequence of the above change.
Schedule 12, Minor and Consequential amendments, paragraph 193 New section 252ZA of the NHS Act 2006 - Code of practice on confidential patient information	This derives from section 263 of the Health and Social Care Act 2012 (which is repealed by paragraph 12 of Schedule 7 to the Bill) and which required NHS England to publish a code of practice on confidential information. New section 252ZA is slightly narrower insofar as it is limited to confidential patient information, but the scope of the code is slightly broader insofar as it covers processing (rather than just collection, analysis and dissemination) of confidential patient information in connection with the provision of health services or of adult social care in England.
Schedule 12 Minor and Consequential amendments, paragraph 196 Section 253 of the NHS Act 2006 - emergency powers	The Bill amends section 253 of the NHS Act 2006 to remove the ability for the Secretary of State to direct NHSE to exercise the Secretary of State's functions under section 253, and give directions to NHSE about exercising functions conferred by directions under section 253, given NHSE is to be abolished.
Schedule 12, Minor and Consequential amendments, paragraph 198	Sections 256(5A) and (5B) of the NHS Act 2006 confer on the Secretary of State powers to give directions to NHSE in relation to

Section 256 of the NHS Act 2006 - power of NHSE and an ICB to make payments towards expenditure of community services	payments towards expenditure on community services. These powers will be amended to enable directions to be given to ICBs.
Schedule 12, Minor and Consequential amendments, paragraph 201 Section 269 NHS Act 2006 - special notices of births and deaths	Section 269 of the NHS Act 2006 provides a power for the Secretary of State to make regulations to set out notification requirements in respect of births and deaths. No substantive change is being made to this power; NHSE is being removed from the list of relevant bodies in subsection (11) which can receive this notification .
Schedule 12, Minor and Consequential amendments, paragraph 280 Section 97(1)(f) and 97(1)(i)(iii) Health and Social Care Act 2012 Conditions: supplementary	Under current section 97(1)(f) and (i)(iii) of the Health and Social Care Act 2012, NHSE has the power to direct that standard or special provider licence conditions may require providers who hold an NHS provider licence to publish certain specified information, and to continue to provide a specified health care service, for the purposes of the NHS for a specified period. With the abolition of NHSE, the Bill confers these powers of direction on the Secretary of State instead.
Schedule 12, Minor and Consequential amendments, paragraph 281 Section 98(1)(a) Health and Social Care Act 2012: Conditions relating to the continuation of the provision of services etc	Under current section 97(1)(i)(i) of the Health and Social Care Act 2012, NHSE has the power to direct that standard or special licence conditions for licensed providers of NHS services may require those providers to continue to provide a specified service (and this power will be conferred on the Secretary of State instead by this Bill). The power under section 98(1)(a) enables such a condition to require the licensed provider to provide information to commissioners or such other

	persons in relation to continuing to provide this service as NHSE directs. With the abolition of NHSE, the Bill will confer this power of direction on the Secretary of State instead.
Schedule 12, Minor and Consequential amendments, paragraph 281 Section 98(4) Health and Social Care Act 2012: Conditions relating to the continuation of the provision of services etc	Under current section 98(4) of the Health and Social Care Act 2012, NHSE must publish guidance for commissioners of a service, to which certain conditions under section 97 of that Act apply, in relation to the exercise of their functions with respect to licensees who provide those services, and to those licensees about the conduct of their affairs, business and property. With the abolition of NHSE, this Bill will confer the duty to publish this guidance on the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 284 Section 102 of the Health and Social Care Act 2012	Section 102 of the Health and Social Care Act 2012 is amended to remove references to NHSE, consequential on its abolition, from the power of Secretary of State and CMA to modify by order provider licence conditions in certain specified circumstances.
Schedule 12, Minor and Consequential amendments, paragraphs 298 and 299 Health and Social Care Act 2012 revised sections 130 and 131	The Bill amends a range of provisions in Chapter 5 of Part 3 of the Health and Social Care Act 2012 relating to health special administration to make consequential changes to the provisions on the abolition of NHSE. These provisions are yet to be commenced. There are numerous amendments to the regulation making powers of the Secretary of State in section 130 of the Health and Social Care Act 2012, which are consequential on the abolition of NHSE. They do not change the identity of the person on whom the power to make the regulations is conferred (it remains the Secretary of State) and they do

	not change the substantive scope of the power or the procedure to which the regulations are subject. The regulation making power in section 130(6)(a) enabling the Secretary of State to require that the Secretary of State publish guidance to commissioners about the criteria in section 129(1)(a) is amended, previously this power being to require NHSE to publish such guidance. Section 131 provides the Secretary of State with a power in those section 130 regulations to make provision about transfer schemes (transferring property, liabilities and staff) to achieve the objective of a health special administration (as set out in section 129). Previously, subsection (2) enabled the regulations to make provision for NHSE to have the power to modify a transfer scheme with the consent of the parties involved. In future, the regulations may enable the Secretary of State to have the power to modify the transfer scheme.
Schedule 12, Minor and Consequential amendments, paragraph 314 Section 234 of the Health and Social Care Act 2012 - Quality standards	Section 234 currently enables NHSE to direct NICE to develop quality standards related to NHS services. The Bill removes references to NHSE from section 234 and transfers its power of direction to the Secretary of State.
Schedule 12, Minor and Consequential amendments, paragraph 317 Section 239 of the Health and Social Care Act 2012	The current section 239 of the Health and Social Care Act 2012 gives the Secretary of State a regulation making power to confer functions on NICE in relation to providing, or facilitating the provision of, training in connection with any matter concerning or connected with the provision of (a) NHS services, (b) public health services, or (c) social care in England.

	Currently, where the regulations relate to the training function for NHS services, these regulations may also provide that the function is subject to directions by NHSE or the Secretary of State. The amendments made by this paragraph of Schedule 11 to the Bill remove reference to NHSE, consequential on its abolition.
Schedule 12, Minor and Consequential amendments, paragraph 331 Section 22 of the Care Act 2014 - exception for provision of health services	Section 22 of the Care Act 2014 confers a power upon the Secretary of State to make regulations requiring local authorities to design and engage in a process for determining disputes with ICBs and NHSE over Continuing Health Care and joint funded health and social care packages. These duties have been enacted via the Care and Support (Provision of Health Services) Regulations 2014. As NHSE is being abolished and some of its commissioning functions are being transferred to the Secretary of State, this minor amendment will allow us to amend the 2014 Regulations, similarly substituting Secretary of State for NHSE. The duty on local authorities to engage in a dispute resolution process will thereafter apply to disputes with ICBs and Secretary of State, rather than ICBs and NHSE.
Schedule 12, Minor and Consequential amendments, paragraph 389 Section 7A of the Medicines and Medical Devices Act 2021 (MMDA)	Currently, NHSE is granted the power to manage information systems relating to human medicines and medical devices. Section 7A gives the "appropriate authority" the power to make regulations about the establishment and administration of information systems by NHSE. The "appropriate authority" is currently defined as the Secretary of State, in relation to England, Wales, Scotland, and the Department of Health in Northern Ireland, acting jointly with the Secretary of State for Northern Ireland. (see sections 2(6) and 9 of the MMDA). Paragraph 387 of Schedule 11 provides for a change to the definition of appropriate authority in relation to section 7A MMDA only, to the

	Secretary of State in England, Wales and Scotland, and to the Secretary of State and the Northern Ireland Department of Health acting jointly in Northern Ireland. In addition, it transfers who may be given operational responsibility under the regulations to establish and operate these systems from NHSE to the Secretary of State. The decision by the Secretary of State to abolish NHSE has resulted in necessary consequential changes to this clause. Specifically, in future, Secretary of State will need to fulfil the responsibilities that are currently given to NHSE to establish and operate these systems in relation to the whole of the UK. Consequential amendments are required to reflect the transfer of functions to the Secretary of State in section 7A to ensure that the regulation-making power in that section can be correctly exercised across the UK. These changes reflect the requirements of the Northern Ireland Act 1998, which prevent the Department of Health in Northern Ireland from exercising regulation-making powers alone where those powers relate to the conferral of functions on a Minister of the Crown. As the Secretary of State will now hold responsibility for establishing and operating the relevant information systems, rather than NHSE, a joint exercise of powers with the Department of Health in Northern Ireland is required.

Schedule 12, Minor and Consequential amendments, Paragraph 391 Section 19 of the Medicines and Medical Devices Act 2021 (MMDA)	Currently, NHSE is granted the power to manage information systems relating to human medicines and medical devices. Section 19 of the MMDA (as amended by the Health and Care Act 2022) confers on the Secretary of State the power to make regulations that allow the NHSE to establish and operate one or more information systems for purposes relating to (a) the safety and performance, including the clinical effectiveness, of medical devices that are placed on the market; (b) the safety of individuals who receive or are treated with a medical device, or into whom a medical device is implanted; and (c) the improvement of medical device safety and performance through advances in technology. The provision makes no change to the powers given to the Secretary of State. However, it transfers who may be given operational responsibility under the regulations to establish and operate these systems from NHSE to the Secretary of State.