

Title: Health and Care Act 2022 Core Measures IA No: 9566 RPC Reference No: RPC-DHSC-5082(1) Lead department or agency: Department of Health and Social Care Other departments or agencies: NHS England	Impact Assessment (IA)			
	Date: 19/07/2022			
	Stage: Final			
	Source of intervention: Domestic			
	Type of measure: Primary legislation			
Contact for enquiries: Not applicable				
Summary: Intervention and Options			RPC Opinion: GREEN	

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
Unquantified	Unquantified	Unquantified	Non qualifying provision

What is the problem under consideration? Why is government action or intervention necessary?

There is stakeholder consensus that greater collaboration within the English health and care system will enable both the NHS and the social care sector to deliver effective and timely care to patients. The need for change is compounded by the increasing complexity of health and care needs of patients, rising demand from an aging population, as well as the challenges of responding, and learning from responses, to health emergencies such as the Covid-19 pandemic. Whilst legislative change alone cannot deliver reform, it can support new ways of working and remove specific barriers created by existing primary legislation. Removing these barriers will be vital to support the NHS and wider health and care system as it recovers from Covid-19 impacts.

What are the policy objectives of the action or intervention and the intended effects?

This Impact Assessment (IA) mainly covers the subset of legislative changes in the Health and Care Act that have the unified aim of supporting the effective delivery of the NHS Long Term Plan whilst strengthening democratic accountability. Within this, the individual measures are broadly aimed at: one, enabling closer working between different parts of the health and care systems, such as through joint commissioning or the establishment of Integrated Care Boards and Integrated Care Partnerships; two, reducing bureaucracy so that commissioning of healthcare services is more effective and services can be arranged to better meet the needs of local populations; three, strengthening accountability for decision-making whilst improving public confidence. This IA also covers some provisions which are not in the NHS Long Term Plan but are closely linked to the three themes of the Act, such as data sharing. The Act also makes some wider legislative changes to tackle known issues with the existing framework; these measures are not covered in this IA.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

This IA covers legislative changes developed by the Department of Health and Social Care, working with a breadth of stakeholders including NHS England, and the Department for Levelling Up, Housing and Communities. These have been developed from horizon scanning of future roadblocks for the health and care system, and, build on some of the legislative changes which NHS England and NHS Improvement previously recommended to the Government in autumn 2019; the latter have been developed after extensive public engagement. The new measures also build on learning from ways of working implemented during the Covid-19 response. Where the policies have not already been implemented, given the breadth of the package of measures in this IA, it is focussed primarily on the leading options for each of the provisions and specific legislative changes. Impacts are by default compared against a 'do-nothing' option.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Not applicable				
Does implementation go beyond minimum EU requirements?		N/A		
Is this measure likely to impact on international trade and investment?		Yes		
Are any of these organisations in scope?	Micro Yes	Small Yes	Medium Yes	Large Yes
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/A	Non-traded: N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:  Date: 19/07/2022

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year N/A	PV Base Year N/A	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: N/A

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			
High			
Best Estimate	N/A	N/A	N/A

Description and scale of key monetised costs by 'main affected groups'

The provisions set out in this IA are complex and also include a number of enabling powers which either lead to practical but limited changes; require secondary legislation or consultation before practical changes can occur; and/or, require system behavioural change before practical changes come into force. It is not possible to robustly estimate an overall cost impact by affected group. An assessment of impacts on businesses, including small or micro businesses, and wider impacts such as those on the environment, trade and competition, will be completed where appropriate alongside secondary legislation.

Other key non-monetised costs by 'main affected groups'

There may be opportunity costs of the provisions which cannot be quantified. For example, if the Secretary of State chooses to exercise new powers of direction over NHS England, any benefits of greater autonomy may be forgone. Other non-monetised costs may include business disruption, such as organisational costs in adapting to new regulations. These are typically sunk costs and are already part of the counterfactual.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			
High			
Best Estimate	N/A	N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'

Benefits relating to empowering organisations, reducing bureaucracy and clarifying accountability have not been monetised in this IA as a robust estimation of likely effects is not possible. Where specific provisions could have their monetised benefits defined these are noted in the relevant sections.

Other key non-monetised benefits by 'main affected groups'

The package of measures clarifies the law and better enables providers, commissioners and local authorities to collaborate and integrate at scale. A move towards greater collaboration in the English health system is widely seen as central to meeting the challenges of rising demand and complex needs. The provisions recognise that responsibility and accountability are pooled across the system, and ensuring strong collaboration between organisations will strengthen the ability of organisations to respond adequately to the challenges facing them.

Key assumptions/sensitivities/risks

Discount rate (%) N/A

The implementation of the provisions will be affected by the ongoing response to Covid-19, and how the system works to recover from this period. There is also a risk – associated with any change programme, even if intended to be limited – that resources are spent on implementing a new system to the detriment of output. However, these risk are expected to be mitigated by the fact that these legislative provisions support the existing changes the NHS has already been pursuing. Some provisions have aims of amending specific pieces of legislation that are not thought to be working well, e.g. provisions on the national tariff to allow for flexibility for local pricing; while others – such as the provisions on competition and joint committees – are expected to reduce bureaucracy for health systems.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	Score for Business Impact Target (qualifying provisions only) £m: Not a qualifying provision	
Costs: N/A	Benefits: N/A	Net: N/A

Health and Care Act: Evidence base for Impact Assessment

Background and Overview

Over the past few years, the health and care system in England has undergone a process of substantial operational change. This evolution, which has been led by the NHS, occurred within the existing legislative framework but often required health and care bodies to find complex workarounds. The legislative framework (which, for example, sets out in great detail the distinct roles and responsibilities for individual organisations in the system) needed to be updated to better support the needs of the health and care system to continue to evolve to meet the changing needs of our population.

Many NHS commissioners and providers, along with local authorities and voluntary sector partners, had already started to implement collaborative working mechanisms. This happened through the creation of new types of integrated provider models, as set out in the Five Year Forward View, and latterly through Sustainability and Transformation Partnerships (STPs) and their evolution into non-statutory Integrated Care Systems (ICSs). As of April 2021, all areas of England are covered by an ICS.

The development of these collaborative mechanisms has been progressing in recent years: all STPs have now become ICSs. NHS England and NHS Improvement set out in their Integrating Care paper: “The response of the NHS and its partners to Covid-19 and a further year of ICS development has increased the appetite for statutory “clarity” for ICSs and the organisations within them. With an NHS Bill included in the last Queen’s Speech, we believe the opportunity is now to achieve clarity and establish a “future-proofed” legislative basis for ICSs that accelerates their ability to deliver our vision for integrated care”¹.

The pre-Act system has complex accountability mechanisms at local and national level. These were largely created by the Health and Social Care Act 2012, which centred on the principles that the NHS should be able to operate through a quasi-market approach, meaning that NHS organisations would be sustained by competition which would be the main driver behind improvements to quality and efficiency. In many ways, the system has not operated as the original policy envisaged, and lack of system alignment is one of the areas highlighted by the service and independent DHSC-funded research² as requiring improvement, especially as the demographic changes that require a stronger emphasis on joined-up care continue. The Health and Care Act creates a more nuanced approach to the competition regime, that gives due weight to collaboration, rather than competition alone. Competition will still play an important role in improving services delivered to NHS patients, for example, through the provider selection regime, strengthened patient choice rights and the Competition and Markets Authorities continued oversight of the private healthcare market.

The Health and Care Act therefore has learnt from of the evolution of the NHS since 2014, and the publication of the Five Year Forward View³, as well as the specific experience of the Covid-19 response, and are expected to enable the NHS to meet the challenges ahead by

¹ NHS England, ‘Integrating care’, 2020, para. 3.8, <https://www.england.nhs.uk/wp-content/uploads/2020/11/261120-item-5-integrating-care-next-steps-for-integrated-care-systems.pdf>

² In 2014 the NIHR DHSC Policy Research Programme funded four projects under the Health Reform Evaluation Programme exploring different aspects of the new health and social care system following the Health and Social Care Act 2012. The four projects explored: the new NHS commissioning system, diversity of healthcare provision, the establishment and operation of Health and Wellbeing Boards, commissioning public health services. A full list of references for this programme of work is provided at Annex A.

³ NHS England, Five Year Forward View, 2014. [Online]. Available from: <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>

making permanent the principles of collaboration and agility of decision-making. Many measures covered in this Impact Assessment (IA) are enabling measures: they either require secondary legislation to come into force (e.g. powers of direction), or they remove some existing requirements without preventing their continued operation (e.g. provider selection).

Scope of the Final Stage Impact Assessment

In January 2019, through the publication of the Long Term Plan⁴, the NHS set out proposals for legislative change to support the NHS to implement the LTP more easily. Following this publication, the NHS engaged with the public, patients, NHS staff and a broad range of representatives from across the health and social care sectors on possible legislative changes. In September 2019, following extensive engagement, NHS England published their final recommendations⁵. **These LTP proposals, which form part of the Health and Care Act, are the focus of this IA; some new measures, closely linked to this core focus, are also considered.**

Nonetheless, the Act goes beyond this core focus and introduces specific changes which will benefit patients and citizens in the years ahead – measures are wide-ranging, spanning areas from professional regulation to hospital food standards⁶. These additional, specific interventions are considered in either standalone IAs, or, the Additional Measures Impact Assessment. The Health and Care Act Impact Assessment Summary Document sets out the IAs completed as part of the Act and where to find them. In many cases, supporting evidence is already in the public domain or consultation processes are ongoing. A list of all measures considered in this IA is specified in Table 1 of the next section.

Unless otherwise stated, future references in this IA to proposals, provisions, policies or measures, refer only to those covered by this analysis, rather than all policies in the Act.

Principles underlying the Health and Care Act

The measures in the Act which directly implement or build on NHS England's original recommendations for legislative change to support implementation of its [Long Term Plan \(LTP\)](#) follow three themes, all of which are integral for helping the system to recover from the pandemic and transform patient care for decades to come. **These three core themes are the focus of this Core IA and are detailed below.**

Alongside these LTP measures, there are additional provisions to make targeted changes to allow the Government to support the social care system, improve quality and safety in the system, to grant the flexibility to take public health measures and to implement worldwide comprehensive reciprocal healthcare agreements. Many of these measures also support the core aims directly or indirectly. They reflect the evolution of the Health and Care System since the Health and Social Care Act 2012. They also encompass opportunities arising from external factors, such increased legislative flexibility following our departure from the European Union, the changes in the way healthcare is delivered because of the coronavirus pandemic, and extraordinary advancements in technology and medicines. More details on

⁴ NHS England, 'The NHS Long Term Plan', 2019. [Online]. Available from: <https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf>

⁵ NHS England, 'The NHS's recommendations to Government and Parliament for an NHS Bill', 2019. [Online]. Available from: <https://www.england.nhs.uk/wp-content/uploads/2019/09/BM1917-NHS-recommendations-Government-Parliament-for-an-NHS-Bill.pdf>

⁶ All legislative proposals for a Health and Care Bill are detailed in the White paper, 'Integration and Innovation: working together to improve health and social care for all'.

the IAs associated to this theme can be found by referring to the Impact Assessment Summary Document.

I. Working together and supporting integration

These provisions intend to make it easier for NHS organisations and local authorities to work together to deliver their health and care functions, given the interdependent nature of these functions. This could be through producing a joint plan of the health and care needs of their local populations; or agreeing for an organisation's functions to be exercised by another body.

II. Reducing bureaucracy

Provisions under this theme intend to remove unnecessary bureaucracy and speed up decision-making processes to enable swift actions. In line with NHS England's recommendations, the aim is to strip out unhelpful rigidities in the legislation, where they fail to enhance accountability, or necessitate complex or bureaucratic workarounds and make it difficult for the system to integrate and adapt over time as needed.

III. Ensuring accountability and enhancing public confidence

While accountability can mean different things in different contexts, a definition offered by the King's Fund in relation to accountability in the NHS illuminates what the provisions relating to accountability in this Act are trying to achieve:

“Accountability typically refers to a relationship involving answerability, an obligation to report, to give an account of, actions and non-actions. This indicates that there is an assumed expectation of the need to **report and explain**, either in person or in writing.

Accountability implies that there may be **consequences** (or sanctions) if the 'account-giver' is not able to satisfy the 'account-holder' that he or she has fulfilled the objectives set or made effective use of the resources allocated. Klein and New (1998) distinguish between 'strong' accountability, where there are sanctions if performance or the account of conduct is unsatisfactory, and 'soft' accountability, where an actor is required to justify performance in public (or at least in a transparent process) but no direct sanctions may apply other than perhaps public shaming.”⁷

In the context of this IA, accountability most frequently refers to arrangements for NHS England to report and explain their actions to the Secretary of State for Health and Social Care, and for the Secretary of State to respond in a range of ways if he is not satisfied with these explanations. The changes in this group also include measures where NHS England might be required to exercise any of the Secretary of State's public health functions.

Many of the provisions will enable changes under more than one theme, as highlighted in Table 1. Shaded squares in Table 1 identify a provisions main theme:

⁷ The King's Fund, 'Accountability in the NHS: Implications of the government's reform programme', 2011, p7. [Online]. Available from: <https://www.kingsfund.org.uk/sites/default/files/Accountability-in-the-NHS-June-Kings-Fund-2011.pdf>

Table 1: Categorisation of proposals considered in the IA by theme

Provision group	Theme		
	I. Working together and supporting integration	II. Reducing bureaucracy	III. Ensuring accountability and enhancing public confidence
1. Merging NHS England and NHS Improvement	X	X	X
2. Establishing Integrated Care Boards and Integrated Care Partnerships in law	X	X	X
3. Joint Committees, Collaborative Commissioning and Joint Appointments	X	X	
4. Triple Aim	X		
5. Duty to Cooperate	X		
6. Care Quality Commission reviews of Integrated Care Systems	X		X
7. Data sharing	X	X	X
8. Foundation Trusts capital spend limit	X		X
9. Competition	X	X	
10. Provider selection and Choice	X	X	
11. National Tariff	X	X	
12. New trusts	X	X	
13. Special Health Authorities Time Limits		X	X
14. Arm's-Length Bodies transfer of functions power	X	X	X
15. General power to direct NHS England	X		X
16a. NHS England Mandate: general (and Better Care Fund)			X
16b. NHS England Mandate: cancer outcome targets			X
17. Reconfiguration of services: intervention powers			X
18. Public Health power of direction	X	X	X
19. Abolishing Local Education Training Boards		X	
20. Workforce accountability			X
21. Designating Integrated Care Boards as Operators of Essential Services under NIS Regulations	X		X
22. Information about inequalities	X		X
23. Further embedding research in the NHS	X		X
24. ICB and NHSE inequalities duty extension			X
25. Climate change duties			X
26. Accountability and Transparency of Mental Health Spending			X

Costs and benefits

It is difficult to predict precisely the occasions when the enabling provisions in the Health and Care Act will be used, as the changes will give health and care organisations greater freedom to collaborate and arrange services in the best interests of their population at a local

level, with appropriate oversight. The impact of the three core themes will therefore vary substantially.

These variations could occur because of the individual organisations involved or the circumstances in which the provisions are being exercised. As a result, the costs and benefits of these provisions are not monetised in this IA. Many of the provisions will not place direct costs on health and care organisations purely by their enactment, with costs only being a possibility at a later stage depending on how organisations choose to deploy the provisions. Where some of the provisions trigger costs – such as with the creation of statutory ICBs – these are expected to be limited and with benefits to the organisation’s wider activities. The Impact Assessment Summary Document highlights where specific impact tests have been undertaken to examine wider impacts of several provisions in this impact assessment. Table 2 summarises whether different measures are expected to: lead to practical changes flowing directly from primary legislation; require secondary legislation or consultation before practical changes occur; and/or, require system behavioural change before practical changes come into force. In the case of the new intervention powers the impact will only be felt directly when Secretary of State makes a direction and intervenes.

Table 2: Categorisation of provisions by principle, and measure impact

Provision group	Principle			Measure impact		
	I. Working together and supporting integration	II. Reducing bureaucracy	III. Ensuring accountability and enhancing public confidence	Practical changes expected to flow directly from primary legislation	Secondary legislation or consultation required for practical changes to come into force	Behavioural change required for practical changes to come into force
1. Merging NHS England and NHS Improvement	X	X	X	X		
2. Establishing Integrated Care Boards and Integrated Care Partnerships in law	X	X	X	X	X	X
3. Joint Committees, Collaborative Commissioning and Joint appointments	X	X			X	X
4. Triple Aim	X					X
5. Duty to Cooperate	X					X
6. Care Quality Commission reviews of Integrated Care System	X		X		X	
7. Data sharing	X	X	X	X	X	X
8. Foundation Trusts capital spend limit	X		X	X		
9. Competition	X	X		X		X
10. Provider selection and Choice	X	X			X	X
11. National Tariff	X	X			X	
12. New trusts	X	X				
13. Special Health Authorities Time Limits		X	X	X		
14. Arm’s-Length Bodies transfer of functions power	X	X	X		X	
15. General power to direct NHS England	X		X			X
16a. NHS England Mandate: general (and Better Care Fund)			X	X		X
16b. NHS England Mandate: cancer outcome targets			X	X		X

17. Reconfiguration of services: intervention powers			X	X	X	X
18. Public Health power of direction	X	X	X	X		X
19. Abolishing Local Education Training Boards		X		X		X
20. Workforce Accountability			X	X		X
21. Designing Integrated Care Boards as Operators of Essential Services under NIS Regulations	X		X	X		X
22. Information about inequalities	X		X	X		X
23. Further embedding research in the NHS	X		X	X		X
24. ICB and NHSE inequalities duty extension			X	X		X
25. Climate change duties			X	X		X
26. Accountability and Transparency of Mental Health Spending			X	X		

Risks and mitigations

The Health and Care Act includes a range of measures that were developed in collaboration with the NHS as part of the wider Long Term Plan proposals (1, 3-6, 8-11 in Table 1). These proposals have undergone wide stakeholder and public engagement, and the policies were informed by that engagement. NHS England and NHS Improvement also published a document exploring options for creating statutory arrangements, which informed the legislative underpinning for Integrated Care Boards which is now included in this Act (2)⁸.

Other provisions considered in this IA, some of which were developed whilst the Covid-19 pandemic was ongoing, had more limited opportunities for public engagement and formal public consultation. However, DHSC worked closely with a range of stakeholders from across the health and care system to develop and refine these proposals, including but not limited to NHS England, the Local Government Association, the Academy of Medical Royal Colleges, NHS Providers, the NHS Confederation and a range of medical trade unions. A full list of stakeholders who were engaged prior to the publication of the White Paper is included in Annex C of that document⁹, and numerous additional stakeholders have been engaged on the Act since then. Finally, the proposals in the White Paper have also been subject to two inquiries by the Health and Social Care Select Committee.

Therefore, whilst there remains a risk as a result of a lack formal consultation with the NHS frontline, other health and care staff and patients, and the public, the substantial engagement undertaken should mitigate that risk. Further, in many cases, the exercise of the powers in the Act will trigger duties to consult and would go some way to mitigate this risk (though this is not the case universally).

As with any legislation, there is an inherent risk that, in making changes to existing legislation, some of the problems which that legislation attempted to solve will, in part, re-emerge. The Health and Social Care Act 2012 was designed in part to drive value by raising the importance of commissioning and competition in the system. The research associated with the NIHR evaluation programme¹⁰ (see Annex A for more detail), and the views expressed by the NHS through its Long Term Plan proposals, point to the conclusion that

⁸ NHS England, 'Integrating care', 2020. <https://www.england.nhs.uk/wp-content/uploads/2020/11/261120-item-5-integrating-care-next-steps-for-integrated-care-systems.pdf>

⁹ 'Integration and Innovation: Working together to improve health and social care for all', 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960548/integration-and-innovation-working-together-to-improve-health-and-social-care-for-all-web-version.pdf page 75

¹⁰ In 2014 the NIHR DHSC Policy Research Programme funded four projects under the Health Reform Evaluation Programme exploring different aspects of the new health and social care system following the Health and Social Care Act 2012. The four projects explored: the new NHS commissioning system, diversity of healthcare provision, the establishment and operation of Health and Wellbeing Boards, commissioning public health services. A full list of references for this programme of work is provided at Annex A.

the improvements envisaged as flowing from that approach did not materialise to the extent that was hoped. In particular, it became more difficult to drive value through the integration of services when they were organised in a more transactional form, provider by provider. The NHS was able to adapt the system to some extent to improve the integration of services and thus to deliver the associated benefits. The Act takes this further, and allows a balanced approach that gives weight to both competition and integration where there are clear patient benefits. In supporting the NHS to continue the journey towards a greater emphasis on integration, it will also be important for the Government to work with the NHS to ensure that the potential (albeit, it would seem, in recent years, largely unrealised) benefits of provider competition remain in view insofar as this is compatible with securing the benefits of integration.

Where risks relate more to individual provisions, they are largely not possible to quantify. As there may be benefits as well as costs arising from the change – and it was not possible, at least at this stage, to monetise how this balance will play out in practice. Before setting out the costs, benefits and risks of each provision, a summary of the evidence surrounding collaboration, agility and accountability is presented for context to these provisions.

The case for working together and supporting integration

The demands on the health and care system are changing. As people are living longer, they are also living with more health conditions, with one in four adults now estimated to live with two or more morbidities¹¹. As the care of people with multiple morbidities is often complex, this requires the interaction between many parts of the health system. These interactions will become more necessary as the burden of multiple morbidities increases, with number of people in England with four or more conditions predicted to double between 2015 and 2035¹².

There is general agreement across the public sector (and across health systems internationally) that lack of alignment of services is inefficient in delivering services to the public and results in worse user experiences. This may “result in gaps for service users, provision may be duplicated, and citizens may be buffeted between several different agencies of service providers”¹³. The integration provisions within the Act allow for more joining up between health, social care and other public services to provide wrap-around care and support that meets individual’s needs.

In health and care, while there is mixed evidence on whether collaboration can provide cost savings in the delivery of services, there is consensus that collaboration between health and care organisations and the reduction of siloed working can and should go further. The evidence for this approach has been set out over an extended period, with collaboration occupying discussions around change in the NHS for many years. This is tied up in the debates around integration of care – although the two terms are sometimes used interchangeably, collaboration between organisations is arguably the *catalyst* enabling the delivery of integrated services to people.

There are mixed results on the impact of collaboration on definitive health improvements, and this prompts further consideration of the benefits of collaboration for structural cohesion, staff, and patient experiences. NHS Improvement has described collaborative approaches

¹¹ Stafford, M., Steventon, A., Thorlby, R., Fisher, R., Turton, C., & Deeny, S. (2017). Briefing: Understanding the health care needs of people with multiple health conditions. Health Foundation p5.

¹² Kingston A, Robinson L, Booth H, Knapp M, Jagger C. Projections of multi-morbidity in the older population in England to 2035: Estimates from the Population Ageing and Care Simulation (PACSim) model. *Age Ageing*. 2018; 47: pp 374–80.

¹³ Blavatnik School of Government, 'Building the tools for public services to secure better outcomes', p 11, <https://s3.eu-west-2.amazonaws.com/golab.prod/documents/BSG-GOLab-EvidenceReport-20190730.pdf>

as ones which “can improve communication, save time, reduce duplication of effort, improve working relationships and provide a better experience for people who use health and social care services.”¹⁴ National Voices (a coalition of charities who advocate for person-centred care) has also emphasised the benefits of integration, as facilitated by collaboration, for patients:

“Achieving integrated care would be the biggest contribution the health and care services could make to improving quality and safety. Patients, service users and carers want continuity of care, smooth transitions between care settings, and services that are responsive to all their needs together.”¹⁵

More recent publications substantiate this view of the broader benefits of collaboration for challenges such as workforce. NHS Providers (the membership organisation for the NHS hospital, mental health, community and ambulance services) has noted the benefits for system leaders in “coming together around a shared aim and recognising that organisations have commonalities which leaders can rally around to develop joined-up workforce solutions”, resulting in reduced competition for staff within the same system and more varied opportunities for individuals to move between organisations.¹⁶

The provisions in this IA are therefore evaluated against the impact which they will have on collaboration within the NHS and between the NHS and local government, considering both how they aid the Covid-19 response and recovery, and whether they provide longer-term benefits for patients, staff and the public.

The case for reducing bureaucracy

Evaluations of bureaucracy across the NHS have been a common theme of healthcare discourse in recent years, with these discussions accentuated by the Health and Social Care Act 2012 reforms and how the system has adapted since these. As well as procedural bureaucracy around issues such as procurement¹⁷, this takes the form of bureaucracy within leadership structures, including how the various leadership organisations within the NHS can send multiple and sometimes conflicting messages to the system.

The new provisions are designed to be enabling and flexible, with a greater emphasis placed in empowering local leaders, recognising that where the legislative framework is too inflexible and proscriptive, it can quickly become a barrier to innovation.

In assessing how NHS structures could improve, the Lord Darzi Review of Health and Care in 2018 noted that “By creating a separate institution for each health system function, the 2012 [Health and Social Care Act] has resulted in confusion at individual provider level, with competing priorities and instructions.”¹⁸ The report recommended many changes to simplify the NHS’s structures at a national and local level which are echoed in the provisions in this IA, including the merger of NHS England and NHS Improvement and simplification of procurement processes.¹⁹ This desire for simplification of the regulatory oversight of the

¹⁴ NHS Improvement, ‘Building collaborative teams’, 2014, p 4. [Online]. Available from: <https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2019/01/Building-Collaborative-Teams-workshop-guide-2014-1.pdf>

¹⁵ Ibid., p 14

¹⁶ NHS Providers, ‘System approaches to workforce challenges in the NHS’, 2019, p 1. [Online]. Available from: <https://nhsproviders.org/media/688878/workforce-briefing-1j.pdf>

¹⁷ Responses to NHS England’s engagement on the NHS Long Term Plan were particularly high in relation to procurement rules (section 75 of the Health and Social Care Act 2012), due to an external online campaign. Of those that responded through the consultation directly, 76% of respondents agreed or strongly agreed section 75 should be revoked.

¹⁸ Lord Darzi, ‘Better health and care for all: A 10-point plan for the 2020s’, 2018, p 49. [Online]. Available from: <https://www.ippr.org/files/2018-06/better-health-and-care-for-all-june2018.pdf>

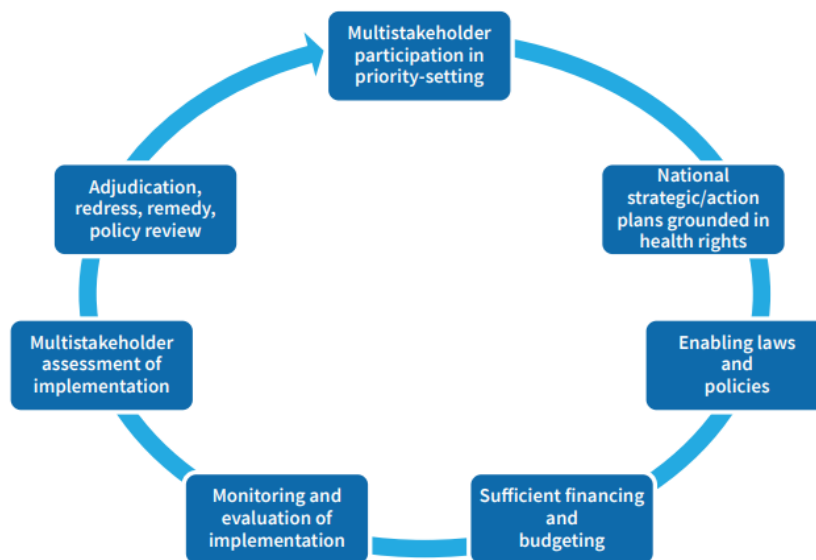
¹⁹ Ibid., pp 51-52

NHS has been echoed in a survey of NHS Trust leaders run by NHS Providers, which identified problems in this area as follows:

“Trust leaders tell us they are optimistic about the potential for new oversight frameworks to hold systems to account for collective performance, and for the alignment of system oversight with regulatory requirements at an organisational level. However, in the absence of legislative change, it will be complex for the national bodies and regulators to reconcile regulation and oversight at organisational level with the policy ambitions for collective accountability at system level.”²⁰

However, there is evidence from the response to extreme events – which has been extrapolated to the Covid-19 response – that there is a balance to be struck in managing these responses between agility and discipline. The King’s Fund has noted that: “The problem is that extreme events present unforeseen conditions and problems. They often require decisive action from central controllers. But they also require adaptation, creativity and improvisation on the ground.”²¹ There is therefore evidence to suggest that a simplification of regulatory oversight, as enabled by legislative change, is desired by the system. However, at this point this should be balanced against the ongoing demands of Covid-19 on the system and a need for some elements of stability to be maintained. The provisions in this IA will therefore be considered against this caveat.

The case for ensuring accountability and enhancing public confidence



The World Health Organisation describes how the circle of accountability helps to reduce health inequity (Figure 1). The accountability provisions assessed in this IA are meant to work as a logical counterpart to the NHS’s longer-term activities, and particularly those developed under the Long Term Plan which provides a ten-year strategic view of NHS activity. Following the implementation of policies in the Health and Care Act, long-term

Figure 1: The circle of accountability to drive health equity

²⁰ NHS Providers, ‘NHS Regulation and Oversight: A time of transition’, 2019, p 31. [Online]. Available from: <https://nhsproviders.org/media/688137/nhs-regulation-and-oversight-a-time-of-transition.pdf>

²¹ The King’s Fund, ‘Discipline and agility in a crisis’, 2020. [Online]. Available from: <https://www.kingsfund.org.uk/publications/discipline-and-agility-crisis>

analysis of these mechanisms should include evaluation of the legislation both within government and with other stakeholders.

The importance of accountability in the administration of public services, and particularly health and care services, is also recognised as a key objective for governments. The World Health Organisation (WHO) has prioritised work with European Member States to strengthen their health systems through improved accountability following the adoption of the Tallinn Charter.²² At the outset, this approach assumed that strengthened accountability would lead to increased transparency and efficiency. However, when evaluating several countries' approaches, it found that:

“the process of institutionalizing new processes and protocols aimed at improving health system accountability involves much more than simply specifying new mandates and enacting legal and regulatory frameworks. Institutionalization also requires investing in capacity building and attention to demand generation in order to promote sustainability.”²³

This suggests that accountability in the provision of health and care services relies upon, in the first instance, the legal basis of accountability within the NHS as a necessary framing context. However, the relationships which emerge from these arrangements also have an important role to play in ensuring accountability. Prior to the implementation of the Health and Social Care Act 2012, the King's Fund noted the importance of this for two roles changed by the reforms:

“We have also identified a number of relationships whose characterisation will ultimately depend on the way in which the account holders interpret their powers and choose to exercise them. This seems to apply to two roles in particular: first to that of the Secretary of State, who has potentially significant powers over the NHS Commissioning Board and [CCGs] but has committed politically to less central intervention in the service; and second to that of the NHS Commissioning Board – its choice of a lighter or heavier approach to performance management when performance assessing [CCGs] will have a significant influence on the culture of the system as a whole.”²⁴

It can be inferred that a similar principle will apply to the provisions affecting accountability considered in this IA, and so these should be considered against the degree of relationship building needed to make them effective. This also goes some way towards explaining why quantifying the impacts of these policies is challenging. As outlined in this IA, the effect of the accountability provisions in the Health and Care Act will depend upon how these new powers are exercised. This diminishes the prospect of a robust *a priori* analysis on how the provisions will affect the system. Furthermore, pre-Act, the Secretary of State can formally use his direction powers to intervene only if the system is actually failing or at risk of failing. This is arguably too late a point to intervene and is a high threshold to pass. The measures ensure that the legislative framework contains updated and proportionate levers for the Secretary of State to set the strategic direction for the system and intervene as required to ensure that strategic vision is being delivered, via a more flexible mandate-setting process and powers of direction.

²² World Health Organization Regional Office for Europe, 'Strengthening health system accountability: a WHO European Region multi-country study', 2015, p 2. [Online]. Available from: http://www.euro.who.int/_data/assets/pdf_file/0007/277990/Strengthening-health-system-accountability-multi-country-study.pdf

²³ Ibid., pp 51-52.

²⁴ The King's Fund, 'Accountability in the NHS: Implications of the Government's reform programme', 2011, p 44. [Online]. Available from: <https://www.kingsfund.org.uk/sites/default/files/Accountability-in-the-NHS-June-Kings-Fund-2011.pdf>

Post Implementation Review

The PIR of the Health and Care Act 2022 will be commissioned through an NIHR Policy Research Programme open-call. DHSC are inviting proposals for a single primary research project to provide evidence on the implementation and impact of the Act. The PIR is focused on the policies in this impact assessment.

The primary interest of the PIR is to understand the different ways that ICBs and ICPs, and system partners (at system, place, and neighbourhood level) are coming together to design, commission and deliver services, and fulfil their duties, and the potential impacts. The aim is to capture learning to identify how positive changes may have been achieved, the obstacles to this (and how these can be avoided), and to disseminate that learning across the system.

This evaluation will help to spread learning in a timely manner (e.g., learn and disseminate what works in delivering quality integrated care and support). It will also support Ministers and policymakers understand how the system is evolving following the legislative changes, how DHSC can best support ICBs and system partners in delivering better outcomes and inform future reforms regarding integrated care.

This evaluation will be a mixed methods and multi-phased study, taking around 2-3 years to complete. However, research outputs will be produced and shared before completion to be disseminated with systems, facilitating the share of lessons learnt and best practice with systems.

Summary of the costs, benefits, risks and mitigations of each policy

This section provides details of each of the Health and Care Act policies designed to support the health and care system. A summary of benefits, costs, risks and mitigations for each provisions is given within the context set out in the previous section.

This section provides details of each of the changes to support the health and care system. A summary of benefits, costs, risks and mitigations for each provisions is given within the context set out in the previous section.

1. Merging NHS England and NHS Improvement

Policy summary

NHS England, and NHS Improvement (comprised of Monitor and NHS Trust Development Authority) have been operating as a single entity to the extent that pre-Act legislation allowed since 2018. The Act allows for the formal merger of the functions of the three main statutory bodies (NHS England, Monitor and the Trust Development Authority) responsible for the NHS into a single statutory body. Monitor and the Trust Development Authority will then be abolished. This merged body – referred to as NHS England in this IA - will have one board and one Chief Executive, and the organisation will be accountable to the Secretary of State. The new organisation will remain a Non-Departmental Public Body. This is intended to provide better aligned priorities and efficiencies, and a legal structure that better reflects how the two organisations already work together.

The public see the National Health Service as a single organisation. Parliament expects the whole of the NHS to work together to make the best use of its collective resources for the greatest benefit for patients. Health and care organisations are increasingly working together to improve care for their populations and want the national leadership to speak with a single voice. As the organisations with most responsibility for setting the direction of and overseeing the NHS, NHS Improvement and NHS England were already working closely together, pre-Act, to align operating models, Board and committee arrangements, and appointments through the joint working programme.

Despite the progress made by the joint working programme, there were limits to what could be achieved under the pre-Act statutory framework. NHS England, Monitor and the Trust Development Authority were assigned some distinctive and non-shareable functions, and primary legislation required separate board governance, chairs and CEOs for the three organisations, even though they were attempting to operate a single leadership model. Furthermore, due to statutory commissioner and provider duties, the organisations still needed to have: separate Audit and Risk Assurance Committees; separate Nominations and Remuneration Committees; separate statutory committees; separate statutory accounts and financial allocations.

Although staff policies and terms and conditions could be aligned, the bodies remained three separate employers – so, for example, to enable directors to exercise the functions of all three bodies they must be jointly appointed and employed by all three bodies (which complicates the employment arrangements). Internal finance involves some complexity in managing three separate budgets and ensuring the correct allocation of funding between the three bodies, while aiming to act as a single organisation.

Costs

Merging organisations can come with associated costs in the short-term including: redundancy packages arising from reducing head count for duplicated functions; transitioning multiple IT systems; transitioning multiple office locations. An attempt to quantify these operational costs was not made as the merger of NHS England, Monitor and the Trust Development Authority was already largely complete pre-Act and so any such costs would have been borne previously. The legal merger formalised the effective merger that was in operation, removing the need for workarounds generated by the previous legislative framework.

Benefits

The merger formally created in law a single body responsible for the oversight of NHS commissioning and provision, thereby aligning a more integrated national landscape with more integrated local systems. It has also created a more empowered, streamlined NHS England to support strategic decision making, with clearer lines of accountability for the bodies underneath it.

While the joint working programme represented progress, forgoing legislative changes the Act provides would have left national bodies operating under complex joint arrangements and managing the unresolved inconsistencies and potential conflicts which arise from the original legislative framework for the three statutory bodies. Changes to the legislation will catch up with the agreed direction of travel at national and local levels. This will have the benefit of tidying up corporate governance and clarifying accountability to government and parliament.

Merging organisations has brought about associated benefits, for example through a reduction in duplicated functions. An attempt to quantify these benefits has not been made as the transition to one single organisation was largely complete Pre-Act.

Risks and mitigations

The formal merger of NHS England and NHS Improvement had limited risks as the joint working programme was largely complete Pre-Act. There is potential for conflicts of interest to arise within the merged organisation where there is not an alignment between NHS England's commissioning functions and the regulatory, support and oversight functions. This is expected to be mitigated through governance arrangements which maintain appropriate separation between functions and manage conflicts of interest, and by new powers of direction from the Secretary of State. In particular, the Care Quality Commission remit, as the independent regulator of health and adult social care in England, will remain unchanged.

2. Establishing Integrated Care Boards and Integrated Care Partnerships in Law

Policy summary

These provisions enable the creation of a new type of statutory NHS body, the integrated care board, to cover the whole of England. It also mandates the creation of a joint committee between each ICB and each local authorities that coincides, wholly or partly, with the ICB area to be known as the integrated care partnership (ICP). ICBs will be the primary commissioning bodies for the NHS, with ICPs providing a forum for strategic planning. NHS England and NHS Improvement consulted on the next steps to building strong and effective integrated care systems across England, which closed on 8 January 2021²⁵. The consultation document outlines that amongst representative bodies, overall, there was a high level of support for developing statutory bodies to build on the work/success of existing ICSs.

Following this consultation (results discussed further below) and extensive discussions with stakeholders, our proposal is that an ICB will be formed in each ICB area. As of April 2021, all areas of England are under the remit of a voluntary ICS, as was outlined in the Long-Term Plan²⁶. Therefore, this will formalise and develop the arrangements already in place on a voluntary basis.

Integrated Care Boards (ICBs) will merge the geographical scale of current voluntary ICSs with the functions of Clinical Commissioning Groups (CCG). All remaining CCGs will be abolished on the day that NHS England must ensure ICBs cover the whole of England. Statutory ICB functions will, in particular, include:

- Developing a plan, jointly with partner NHS trusts and foundation trusts, to meet the health needs of the population within their defined geography; and
- Securing the provision of certain health services to meet the needs of the defined geography's population.

The board of each **Integrated Care Board** will be responsible for day-to-day decisions and oversight of committees and subcommittees of the board. The board will, as a minimum, include a chair, the CEO, and at least one member nominated jointly by NHS trusts/NHS foundation trusts that provide services in the ICB area, at least one member nominated jointly by any primary medical care provider in the ICB area, and at least one member nominated jointly by the local authorities whose areas coincide with the ICB area. ICBs may also decide to appoint further members, which is within their discretion to determine locally.

²⁵ NHS England, 'Legislating for Integrated Care Systems: five recommendations to Government and Parliament', 2021. [Online]. Available: [Report template - NHSI website \(england.nhs.uk\)](https://www.nhs.uk/longtermplan/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf)

²⁶ NHS England, 'The NHS long-term plan', 2019. p 29. [Online]. Available: <https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf>

At least one member must have experience of working in mental health. ICBs will need to keep under review and take steps as required to maintain the skills, knowledge and experience of the board to ensure it can effectively carry out its functions. ICBs will also need to ensure they obtain appropriate clinical advice when making decisions. NHS England are expected to issue guidance on the membership for ICBs.

Integrated Care Partnerships will take the form of a joint committee with representatives ICB and each upper-tier local authority in its footprint as statutory members. The ICP will be able to nominate further members, so membership is expected to be drawn from a wider group of organisations. This Partnership would be tasked with promoting partnership arrangements, and developing a strategy to address the health, social care and public health needs of their system. Each ICB and Local Authority would have to have regard to this plan. The Partnership will be promoting collaboration and it would not impose arrangements that are binding on either party, given this would cut across existing Local Authority and NHS accountabilities.

Formally establishing ICBs as statutory bodies is necessary because there are legislative constraints on the ability of organisations within a voluntary Integrated Care System to make decisions jointly. In order for voluntary Integrated Care Systems to progress further, legislative change is required to ensure stronger and more streamlined decision-making authority, and to embed accountability for system performance and delivery into the accountability arrangements of the NHS to Government and Parliament. While systems have found ways to establish effective governance models, obstacles and limitations in the current legal framework remain. For example, there is no legal basis at present for CCGs, NHS trusts and FTs to form a joint committee to which functions may be delegated and which makes decisions on behalf of the members.

In exercising its functions an ICB has a duty to have regard to the need to reduce inequalities between persons with respect to their ability to access health services and reduce inequalities between patients with respect to the outcomes achieved for them by the provision of health services. A government amendment has been passed which makes clear that the outcomes referred to include the quality of the experience a patient has alongside the effectiveness and safety of the services.

Palliative care

As a matter of law, the commissioning of palliative and health-related end of life care is already part of the requirements placed on Clinical Commissioning Groups (and Integrated Care Boards, in future) to arrange for the provision of certain health services it considers necessary to meet the reasonable needs of its population.

A government amendment to the Health and Care Act was added in March that clarifies palliative care is a service in scope of the commissioning duty. The amendment does not alter the scope of the duty. It does not place any requirement or expectation on ICBs to commission services that would be better classed as social care or non-health services.

As a result of the fact that ICBs are already expected to commission appropriate palliative and end of life care services from within their existing budgets, we do not expect there will be any additional cost pressures as a result of the amendment.

Overall, NHS England recognises that individual ICBs will need to manage their locality's potential growing need for Palliative and End of Life care resulting from the ageing population alongside other financial risks within the overall health budget.

Costs

ICBs and ICPs will take on the functions of CCGs along with some of the roles currently fulfilled by the current non-statutory ICSs. These reforms therefore build on and cement the arrangements which the NHS and local partners have been evolving towards for several years, with different parts of the country having moved at different speeds. It is intended that the legislation will reinforce and speed up implementation of these arrangements. However, it is difficult to quantify overall savings from this approach, particularly as the movement to the new system has evolved over time, rather than at a particular date from which up-front costs can be attributed. Given that the Act in part formalises what is already in place, and voluntary Integrated Care Systems are already up and running, many of the specific costs faced by new ICBs have already been borne.

The formal abolition of existing CCGs, and the subsequent establishment of ICBs can bring financial and opportunity costs in the form of business disruption, potential re-location and new IT infrastructure. The integration of the NHS with other organisations (such as local authorities) may add complexity which would need to be carefully managed at a local level with respect to accountability and governance. However, the CCG merger programme has already reduced the number of CCGs to 106, from 213 in March 2013 and CCGs have been working ever more closely with local authorities in recent years, we expect these costs to have already largely occurred.

As there will be fewer ICBs (42) than the number of CCGs (~135 in 2021), the number of CCGs transitioned to an ICB will be reduced leading to potential costs with limited numbers of very senior staff redundancies. It is hoped, however, that the provisions minimise the impact of organisational change on staff. NHS England have made a continued employment promise for staff carrying out commissioning functions, with a commitment not to make significant changes to roles below the most senior leadership positions. Furthermore, it is expected many of these costs are sunk costs, already absorbed in the existing CCG merger programme – the NHS Long Term Plan characterised every volunteer Integrated Care System as needing streamlined commissioning arrangements, typically involving a single CCG for each area. As of July 2020, 104 CCGs had merged into 20, with the remaining 115 CCGs being supported to transition by April 2021²⁷. NHS England have also committed that the vast majority of CCG staff will transition to roles in the ICB.

There will be administrative costs from running the new statutory arrangements, although it is difficult to assess whether these costs will be higher or lower than running the current system. Firstly, administrative or running costs will vary between ICB areas and will be somewhat dependent on how the ICB is structured internally. For example, some ICBs may require more place-based structures than others, and so calculating as a meaningful 'average cost' (which may be summed across the system to estimate a total potential administrative cost) based on systems that have already transitioned cannot be calculated. It will be incumbent on each ICB to make sure that its costs are proportionate and beneficial for the work they will be undertaking. Secondly, under the proposed system, ICBs will take on further responsibilities in addition to CCGs current remit, meaning that the running costs of CCGs and ICBs are not comparable. This means current CCG administrative cost data cannot be used as a counterfactual to compare to ICB administrative costs. There may also be opportunity costs for ICP members such as local authorities who will dedicate some resources, such as administrative resources, to participation in the ICP.

The ICB is prohibited from appointing someone as a member if they consider that the appointment could reasonably be regarded as undermining the independence of the health service because of the candidate's involvement with the private healthcare sector or

²⁷ NHS England and NHS Improvement, CCG Mergers April 2021 and beyond. [Online]. Available: <https://localdemocracyandhealth.files.wordpress.com/2020/07/nhscccgmergerswebinar15july.pdf>

otherwise. We expect this to prevent, for example, directors of private healthcare companies, significant stakeholders of private healthcare or lobbyists from sitting on a board of an ICB, where these individuals have views or interests contrary to the aims, values and principles of the NHS. This amendment is not expected to have any significant costs on businesses. While private providers are not allowed to sit on ICBs, they are allowed to sit on ICPs. However, Integrated Care Partnerships will not make commissioning decisions or enter into arrangements that are binding or make decisions about funding allocations, these are functions conferred on the ICB. Therefore, the membership of individuals from private providers on this integrated care partnership does not present a conflict of interest in that way. A risk of this approach may be that private provider views are not taken into account when decisions are made on ICBs, thus reducing the quality of commissioning. However, ICBs (and committees thereof) will have discretion to invite views from private providers where appropriate. There are also other ways than membership that outside views can be taken into account by an ICB, in particular through ICBs' consultation duties and their requirement to obtain expert advice. Further, the risk is mitigated by the legal requirement that ICBs must have due regard to the strategy of the ICP which will have private provider views taken into account.

We do not expect there to be additional costs from adding experience to the *duty to have regard to the need to reduce inequalities alongside access and outcomes*. The experiences of patients and their family and friends are already a key component of the quality of healthcare. Improving patient experience has been an important objective for healthcare for some time with rights such as being treated with dignity and respect being set out in the NHS Constitution. Since the Health Act came into force in 2010, commissioners and providers have had a legal obligation to take the Constitution into account in decisions and actions including focusing on experience. Furthermore, the NHS Outcomes Framework makes clear that the provision of a 'good experience' of care for patients is a central goal for the NHS, making up one of the five core domains. Patient experience is therefore seen as a central outcome for the NHS together with clinical effectiveness and patient safety.

Overall, we expect there to be some additional costs from the establishment of ICPs and ICBs in law, however we expect these costs to be relatively small given that much of this legislation is formalising existing arrangements such as voluntary ICSSs.

Benefits

The policy formalises the way in which local partners already collaborate with each other, providing a clear standard for each ICB area and creating a mechanism for ICB partners to make joint decisions for the benefit of their local population. These will both enhance collaboration within systems by ensuring that ICBs can work together to progress on individual goals, and if these involve compromises, they must be to the satisfaction of all members.

Furthermore, a prescribed membership makes health and social care equal partners within the Integrated Care Partnership, as well as involving Local Authorities in nominating members to the ICB, something which has not been necessarily the case with the informal arrangements used so far. As well as the need for NHS and local government collaboration being demonstrated by the experience of Covid-19, the Health and Social Care Select Committee, when previously examining NHS England's proposals for legislative change, emphasised that *"Local authorities must be part of the decision-making process in order for integrated care systems to be truly place-based and focused on population health."*²⁸

²⁸ Health and Social Care Select Committee, 'NHS Long-term Plan: legislative proposals', p 38, <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/2000/2000.pdf>

By enabling local authority participation will drive integration through pooled budgets and joint working arrangements.

In relation to the duty regarding health inequalities, by explaining that outcomes from services includes a patient's experience of those services, alongside safety and effectiveness, makes explicit what had previously been implicit and recognises the increasing importance given to patient experience in recent years. As a result, all three limbs of inequalities are explicitly mentioned in the duty i.e. access, outcomes and experience. This emphasis on the importance of patient experience is entirely consistent with the NHS 2022/23 priorities and operational planning guidance which says:

“Effective partnership is crucial to achieving the priorities set out in this document. After several years of local development we have established 42 integrated care systems across England with four strategic priorities:

- *improving outcomes in population health and healthcare*
- *tackling inequalities in outcomes, experience and access*
- *enhancing productivity and value for money*
- *supporting broader social and economic development”*

Risks and mitigations

The primary risk attached to this provision is that it does not strike the right balance between improving service and system integration and avoiding an excessive NHS restructuring. Stakeholders have repeatedly argued that a fundamental restructuring of the NHS is not wanted by the system at this point.²⁹ Research³⁰ associated with the NIHR evaluation programme³¹ points out:

“The changes embodied in the HSCA12 were complicated and far-reaching. [...] The fragmentation of commissioning responsibilities was experienced as a particular problem, with [...] complicated ‘workarounds’ required to manage the new complexities. There was no clear evidence that the creation of CCGs as GP-led organisations had led to tangible improvements in commissioning, although both clinical and managerial respondents were enthusiastic about the role played by local clinicians.

*The loss of Strategic Health Authorities as a regional tier of co-ordination was experienced as problematic. The exact impact of the changes was context-dependent, with local organisations responding to their particular local and historical contexts. Our study was completed before any impact of STPs had been felt, but **our findings suggest that, without clear statutory roles and authority, the creation of new regional-level organisations will not automatically lead to improvements in commissioning, nor will it solve the problems that we have highlighted associated with fragmentation of commissioning responsibilities.**”*

To resolve the problems presented by these statutory arrangements, the Act seeks to keep the mandated elements of ICB and ICP functioning to a minimal framework of requirements, while allowing them to go further if locally appropriate. NHS England and DHSC will also

²⁹ Health and Social Care Select Committee, 'NHS Long-term Plan: legislative proposals', p 35, <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/2000/2000.pdf>.

³⁰ Checkland et al, 'Understanding the new commissioning system in England: contexts, mechanisms and outcomes', 2018. [Online]. Available from: <https://prucomm.ac.uk/2018/11/30/understanding-the-new-commissioning-system-in-england-contexts-mechanisms-and-outcomes/>

³¹ In 2014 the NIHR DHSC Policy Research Programme funded four projects under the Health Reform Evaluation Programme exploring different aspects of the new health and social care system following the Health and Social Care Act 2012. The four projects explored: the new NHS commissioning system, diversity of healthcare provision, the establishment and operation of Health and Wellbeing Boards, commissioning public health services. A full list of references for this programme of work is provided at Annex A.

Policy summary

Legislative provisions in this chapter set out a range of measures to support closer working within ICBs and between NHS providers (NHS trusts and foundation trusts) to support the implementation of integrated care and other collaborative arrangements locally.

Many local areas are exploring ways of working more collaboratively and are seeking to align decisions and pool budgets between CCGs and NHS England, across CCGs, and between CCGs and local authorities (LAs). Existing legislative mechanisms make it difficult to do this in all circumstances, meaning local systems need to adopt complex workarounds to be able to make lawful decisions across a wider population footprint. In practice, these arrangements can be cumbersome, difficult to manage and can slow down decisions. With consequential amendments from the ICS reforms this issue will be transferred to the new ICBs (see section 2). It is therefore desirable to change the legislation to streamline and strengthen the governance for this type of decision-making.

NHS England has responsibility for directly commissioning a range of services, including primary medical care, essential and additional pharmaceutical services, dental care, certain public health (“s.7A”) services and specialised services. In a more integrated system, commissioning of these services can be disconnected from wider pathways of care unless delegated to CCGs (which will become ICBs). This can lead to fragmented care, creating risks and issues in the system, and potentially resulting in a poor experience for patients.

Enabling ICBs to have more flexibility in who they commission services with and how will reduce the frequency with which services are commissioned in isolation of the wider care pathway, enabling greater integration of services, reducing fragmentation and improving patient experience. Although with ICBs taking on commissioning responsibilities there will now be one NHS commissioner per system, the flexibility for ICBs to collaborate to commission services across several systems where appropriate is also crucial in ensuring good value and outcomes.

The provisions covered in this chapter are:

- 3a. To allow ICBs and NHS providers to create joint committees.** This includes creating provisions relating to the formation and governance of these joint committees and the any functions exercisable by a body could be delegated to them, with a regulation making power that specifies where the power does not apply; and allow NHS providers to form their own joint committees. Local and combined authorities can be part of these joint committees but cannot share their functions through them (there are existing mechanisms such as section 75 of the National Health Service Act 2006 that allow local authority functions to be shared).
- 3b. To allow ICBs to carry out delegated functions, as if they were their own, to avoid the issue of ‘double delegation’.**
- 3c. That groups of ICBs should be able to use joint and lead commissioner arrangements to make decisions and pool funds across all their functions.**
- 3d. Enable NHS England to jointly commission s.7A public health services with one or more ICBs, or groups of ICBs** or to delegate commissioning of these services to an ICB to carry out that function.
- 3e. Enable NHS England to enter into formal joint commissioning arrangements with ICBs** including providing the ability to pool budgets in relation to specialised commissioning.
- 3f. To introduce a specific power to issue guidance on joint appointments,** with a view to providing greater clarity on such appointments across different organisations.

These measures complement the provisions to create ICBs and ICPs that can bring together partners from across the system.

Costs

Allowing the flexibility for NHS England, ICBs and NHS providers to delegate functions, create joint committees or to make joint appointments has no direct cost. The legislative change will enable local organisations to move to this way of working if deemed to be locally beneficial and appropriate.

The costs or savings from these provisions will depend upon how effectively NHS bodies and their partners are able to improve arrangement of their services. These provisions affect how NHS bodies work together to commission and arrange services, so the equivalent annual net direct cost to business has not been estimated.

Benefits

These proposals are expected to have several benefits. These benefits include: supporting multiple ICBs to collaborate and arrange services for their combined populations (3a, 3b), streamlining decision making, saving time and resources for commissioners (3c); providing more local input into the commissioning of services (3d); and enabling better focus on prevention and pathway design to support shorter length of stays for patients (3e).

Commissioners and providers currently have to use workarounds with complex governance arrangements in order to jointly discuss integrated care, incurring legal risk and administrative cost. This proposal could reduce those costs for organisations that move to this way of working, where deemed to be locally beneficial and appropriate.

Joint appointments of executive directors can help to foster joint decision making, enhance local leadership and improve the delivery of integrated care. They can also help to reduce management costs and engender a culture of collective responsibility across organisations.

Risks and mitigations

A potential risk of moving to closer working is a lack of accountability and transparency in local decision making at organisational level. However, mitigations of this are set out below, and as such, the risk is judged to be low. The NHS Long Term Plan already specifically described existing voluntary ICSs as needing to be transparent and publicly accountable. New guidance will set out how joint committees of commissioners and providers will achieve this and will cover matters including membership of joint committees, their formation, procedures to be followed when making decisions and functions which should not be exercised by a joint committee.

Delegation of NHS England functions will only happen on terms that NHS England consider appropriate. The Act also provides specific safeguards to be introduced in secondary legislation where necessary. Specialised commissioning policy and service specifications will continue to be led at a national level, ensuring patients have equal access to services across the country. NHS England may in future, monitor and set expectations for the ICB under the performance framework.

When making joint appointments, there is the potential for conflicts of interest. The Act allows NHS England to issue statutory guidance that can describe the criteria that organisations should use to assess whether a joint appointment should be pursued, including whether effective arrangements to manage the conflicts of interest could be put in place.

4. Triple aim

Policy summary

A new shared duty will be introduced that requires those organisations that plan services in a local area (ICBs) and nationally (NHS England), and NHS providers of care (NHS Trusts and Foundation Trusts) to have regard to the 'triple aim' of better health and wellbeing for everyone, better quality of services for all individuals, and sustainable use of NHS resources. This includes having regard to inequalities in health and wellbeing and inequalities in the benefits from services. In the Health and Care Act the duty is referred to as the "Duty to have regard to wider effect of decisions".

The aim of the shared duty is to enable closer working between organisations. It should be seen in the context of the other provisions set out in this IA as a supporting measure that will encourage and enable greater collaboration and integration of care.

In having regard to the triple aim, organisations will be expected to:

- Demonstrate compliance for example as part of the annual report, via board papers, or the website
- Consider the Triple Aim in their decision making
- Cooperate with others (most likely through ICBs they are already a part of)

Costs

In complying with the triple aim, it is possible that there is an opportunity cost to the individual organisation, as they take decisions that are for the greater good, rather than their own benefit. For example, one Trust may decide that it is in the best interest of the system that it closes a particular ward, resulting in lost revenue, if there are others of the same specialism in close proximity.

Benefits

Under the current legislative framework, organisations work primarily in the best interest of their immediate patients and place significant emphasis on their duties as independent organisations.

The improvements in quality of care that are set out in the NHS Long Term Plan rely on alignment around a common set of objectives, a shared view of the challenges facing a system and a shift towards integrated systems of providers and commissioners.

The Triple Aim Duty encourages the bodies that are subject to the duty to work collectively, and in the best interest of not only their immediate patients, but of the wider population including considering how their decisions effect inequalities in the health and wellbeing of and benefits from services for that population.

Given the supporting nature of this provision it is not possible to quantify the benefit directly. However, as it is intended to reinforce other provisions, we expect that the triple aim will support the integration of care.

Risks and mitigations

This provision enables and supports the potential effectiveness and benefits of other policies in this Act (e.g. more flexible financial arrangements). Thus, the benefits derived from this provision will be depend on the success of the other measures to deliver beneficial system change. The extent to which the triple aim has an impact will also depend on the enforcement and implementation of the duty. NHS England has a wide range of existing

enforcement tools and guidance where the Triple Aim could be used to help facilitate organisational collaboration.

There is a potential risk that the impact of the measure is limited by the health systems financial structures. As trusts currently report their accounts independently this may reduce the incentive to take decisions for the greater good of the system if a decision directly and negatively affects individual organisations' financial positions. A mitigation to this is that working across systems creates increased opportunity for costs to individual organisations from one decision to be offset by savings resulting from other decisions.

The creation of any new legal duty carries some litigation risk for the bodies that are subject to the duty. It is possible that the application of the new duty could result in additional Judicial Review challenges, where it is contended that a decision maker has failed to have sufficient regard to the triple aim in its planning or decision making.

The wording of the duty has sought to mitigate the litigation risk. The duty is framed as one of "having regard" to "all likely effects" of a decision on the three limbs of the Triple Aim duty. The duty is not intended to require a particular decision in any given case but rather, that decision makers must substantively consider the factors set out in the three limbs of the duty, including inequalities in limbs one and two. Decisions concerning the treatment of individual patients are specifically excluded from the duty, thus removing one significant area of potential legal challenge. NHS England will be able to publish guidance on the Triple Aim, which will assist bodies in complying with the duty.

Ultimately, where bodies are engaging in robust decision-making following proper engagement and consideration of the issues and system implications – the behaviour which the triple aim duty is designed to encourage – we consider that the risk of successful legal challenge to their decisions will be low.

5. Duty to cooperate

Policy summary

The NHS 2006 Act contains duties to cooperate between NHS bodies, and between NHS bodies, on one hand, and local authorities on the other. It is the intention to strengthen these duties by enabling the Secretary of State for Health and Social Care to issue statutory guidance on what cooperation means in practice. English bodies subject to the cooperation duties, will have to have regard to the statutory guidance. The first cooperation duty applies to: NHS England; ICBs; NHS Trusts and Foundation Trusts; Special Health Authorities; some arm's length bodies such as NICE, NHS Digital and Health Education England. The second duty applies to interactions between NHS bodies and local authorities.

The existing cooperation duties have not proved enough to drive the system towards full cooperative working under normal circumstances. However, the response to Covid-19 has demonstrated the system's ability to cooperate at pace during times of crisis, and many parts of the system are now looking to embed these changes in their ways of working through the remainder of the Covid-19 response and beyond. To ensure that these changes are not concentrated only in certain areas the guidance will make it clear to the entire system where cooperation is essential.

These provisions complement the commitment to have ICBs and ICPs (section 2) that which bring together commissioners, trusts, primary care networks, local authorities, the voluntary and community sector and other partners.

Costs

While the legislation will not require organisations to be formally assessed on their adherence to the duty, there may be some reporting costs associated with organisations demonstrating application of this duty. The scope of these will depend on whether anything about reporting is set out in the subsequent guidance. Otherwise, costs associated with the addition of guidance to the duty to cooperate should be minimal, as this should impact primarily *how* organisations work rather than *what* they are doing.

Benefits

This change will strengthen the impetus for individual organisations to work together and requires them to consider how to cooperate effectively. However, it will also be flexible allowing organisations to implement cooperative working in ways which suit them. It will arguably provide a stronger and clearer signal to the system than is currently given through existing duties, making obvious what the system should be working towards out of necessity.

The guidance also applies to local authorities, supporting existing joint working arrangements and creating a further binding connection between the work of the NHS and local government. This will reflect the importance of collaborative working and support the effective operation of statutory ICBs.

Risks and mitigations

This provision enables and supports the potential effectiveness and benefits of other policies in this Act (e.g. appropriate joint working by ICBs). Thus, the benefits derived from this provision will be dependent on the success of the other measures to deliver beneficial system change. The extent to which the statutory guidance has an impact will also depend on its enforcement and implementation.

There is a risk that statutory guidance issued by the Secretary of State will not be a strong enough incentive for organisations to cooperate effectively across the system. However, as well as cooperation largely being in the best interests of the health and care system, this duty will complement the wider changes in the Act which are intended to support system approaches and increasingly joined up working across the bodies that deliver health and care.

6. Care Quality Commission reviews of Integrated Care Systems

Policy summary

The Care Quality Commission (CQC) is the independent regulator of health and social care in England. The Act, following a recommendation from the Health and Social Care Committee, introduces a new role for the CQC in reviewing across each local Integrated Care System. These reviews will look broadly across Integrated Care Systems, and assess the provision of NHS, public health, and adult social care, the activities of the Integrated Care Board, local authorities, and providers in relation to that care and the functioning of the whole system including for example the Integrated Care Partnership.

The Secretary of State must set the objectives and priorities for the reviews of Integrated Care Systems and approve the indicators and methods, allowing the Secretary of State to set the strategic direction of the reviews, and ensure they align with and complement existing assessments. The Act specifies that the priorities must include the themes of Integration, Leadership, and Quality and Safety. They will provide the public and the system with independent assurance of how their area is performing and in particular the

effectiveness of joined up working and integration. This will complement the wider work in the Act through providing an independent assurance of how effective systems are at working together and improving the care people receive.

It is the intention that the CQC will work collaboratively to develop the approach to these reviews, and therefore the design of the inspection regime has not yet been finalised. DHSC worked with CQC to establish the potential impacts of this provision.

Costs

It is not currently possible to make an accurate estimate of costs for CQC ICS reviews as the CQC has not at this time determined or tested the methodology. All 42 ICS would be subject to these reviews. Discovery work by the CQC will be undertaken to define the potential scope of the reviews, but until that work has been completed, the resources required to undertake reviews cannot be stated. There is no easily comparable activity we could use to estimate the costs. For example, the CQC's *Local Systems Reviews* had a different scope and ICSs have a larger geographical footprint.

As an example of costs, for illustrative purposes only, it may be that there would be some implementation and familiarisation costs for the CQC in setting up the system of reviews. This may include new infrastructure to collect data or training staff to undertake the reviews. It is the intention to minimise these costs. There may also be cost on CQC resources as these reviews would be in addition to their existing responsibilities, although this may be mitigated as the reviews should aim to avoid duplication. These reviews will build on much of the evidence that the CQC already gathers through its ongoing regulatory activities of providers and as introduced in the Act, local authority functions relating to adult social care. We expect that any new evidence gathered for these reviews may, for example, relate to system leadership and collaboration between system partners.

There may also be familiarisation costs for organisations in the system, as they will have to comply with any inspection requirements (as is the case for all health and care organisations registered with the CQC).

There may also be ongoing costs for organisations to comply. It is the intention to minimise these costs. As the dimensions that the ICS will be assessed against have not been finalised, it is not possible to give an accurate costing for each inspection. The CQC are due to consult on the nature of these reviews and due consideration for the impact of the reviews will be made at that point.

In terms of the funding for these reviews, the CQC has a statutory responsibility to consult on any changes to its fees scheme and an impact assessment examining the potential effect of fee changes would be produced at that point.

Benefits

This provision, alongside a range of provisions in the Act, will encourage system partners to work together as part of the Integrated Care System as a whole to deliver effective care. The reviews themselves will help improve systems by identifying their strengths and the challenges they face. Repeat reviews, with the ability to map progress against previous performance can themselves be an impetus for improvement. The CQC are also intending for these reviews to inform their reviews of providers and local authorities, thus it has the potential to enhance the CQC's other regulatory work. Finally, the CQC reports will provide an independent assessment of how well areas are performing providing decision-makers and the public with information about the quality and care and joint working within each area. This has benefits in terms of greater transparency in the quality of care provided in ICSs.

Risks and mitigations

There are a range of oversight measures in the system including NHS England's performance assessment of ICBs, and the CQC assessments of providers and the proposed local authority adult social care assurance. There is a risk of duplication, and, if they are not effectively aligned that there could be conflicting reports on the quality of performance.

The CQC will work collaboratively with NHS England and other system partners as they develop their methodology and approach. This is intended to minimise overlap and avoid inconsistency. As the amendment also gives the Secretary of State a role in setting priorities and objectives and approving the indicators and methods, the Secretary of State can ensure that these reviews align and complement existing assessments.

7. Data sharing

Policy summary

The Act makes several changes regarding the collection of data in the health and social care sector:

7a. Introduce powers for the Secretary of State to require information from all regulated adult social care providers about themselves, their activities connected with the services they provide in England (whether funded by local authorities or privately by individuals) and the individuals to whom those services are provided (in England or outside England where the services are commissioned by English local authorities). This will enable government to request data from the adult social care sector to assist with evolving situations, including Covid-19, plan for care provision and maintain oversight of the system. The nature of the information required may change over time.

7b. Enable health and social care public bodies to require the provision of anonymous information (i.e. information other than personal information) from other such bodies and from private bodies providing health and adult social care services under arrangements with such public bodies in connection with the provision of health services or adult social care in England. This, together with commitments on information governance in the data strategy for health and social care, is intended to influence the data sharing culture in the NHS so that information is shared appropriately for the benefit of everyone using health and care services and the running of the system as a whole.

7c. (i) Place a duty on NHS Digital to have regard to the need to (a) promote the effective and efficient planning, development and provision of health services and adult social care in England when exercising its functions, such as processing and sharing information, and (b) balance this and other needs to which it must have regard under section 253(1) of the 2012 [Health and Social Care] Act with each other. (ii) Clarify that the purposes for which NHS Digital can disseminate information are purposes connected with the provision of health care or adult social care or the promotion of health. (iii) Enable NHS Digital to require information from private providers of health care (for the purposes of complying with the Secretary of State's direction to collect information). The current legal framework does not expressly cover (i) and (ii) and hence this is being expressly provided for. The powers in relation to private health care providers will support a consistent and transparent approach to the processing of data across privately and publicly funded healthcare to support improved safety and quality of provision.

7d. Introduce a requirement to comply with information standards and ensure that these can be applied to private providers. Information standards are standards relating to the processing of information (including how it is collected and stored) and can currently apply to public health and adult social care bodies and to health and social care providers acting pursuant to arrangements with such bodies (in addition to the Secretary of State). The purpose of information standards is to ensure that data flows through the system in a usable way and so that when it is accessed/provided (for whatever legitimate purpose) it is in a standard form, both readable by, and consistently meaningful to, the user/recipient.

7e. Enable the introduction of regulations to impose financial penalties on private providers who, without reasonable excuse, fail to comply with an information standard, fail to comply with a requirement to provide information, or who provide false or misleading information.

The need for the new power enabling the Secretary of State to require information (7a) has become more prominent during the Covid-19 response, during which information has been provided voluntarily by social care providers (albeit incentivised by being one of the conditions of receiving monies from the Infection Control Fund until March 31st 2022) and informed DHSC's assessment of the risks and issues faced. Information provided has allowed a consistent approach to DHSC's response and underpinned Care Home Support Plans. However, the data collected is not uniform, and there are gaps that impact on DHSC's ability to proactively respond to provider risks. If this power is exercised it will support ongoing oversight of the adult social care sector and inform policy development. This enabling power is intended to work in tandem with the new power (7c (iii)) which enables information to be required from private healthcare providers, and the new power (7b) which provides a clear statement of intent that where information can be shared, it should be.

Provision 7b is intended to provide that anonymous information that is already held by private health and social care providers can be shared as needed for the ultimate benefit of the health and adult social care sector. As set out below, we intend that the provision will only be commenced following the introduction of regulations setting out exceptions to the duty to comply with a request.

The new duty (7c (i) - (ii)) will emphasise NHS Digital's duty to have regard to wider matters namely the effective and efficient planning, development and provision of health and social care, including treatment, diagnosis or assessment of needs, and also the effective planning and development of that care, such as population health management, risk stratification, audit, policy development, research, and commissioning of services at national and local levels. This, along with the duty to have regard to the need to balance the various needs to which NHS Digital must have regard, will clarify in law how NHS Digital's duties under the Health and Social Care Act 2012 must be exercised safely and securely, to ensure it is able to maximise benefits to the health and care sectors and those that use its service. The new power enabling NHS Digital to require data from private providers will support work to improve the quality and safety of private and NHS healthcare by developing a common set of standards for data collections, performance measurement methodologies and reporting systems across the NHS and private healthcare.

The mandating of standards for how information is processed across the health and social care sector (including by private providers) (7d) aims to ensure standards can be set that improve interoperability of systems and effective data exchange. Existing legislation only requires persons to have regard to standards (though they would need a compelling reason not to do so) and only applies to public health and social care bodies and providers acting pursuant to arrangements with such bodies (in addition to the Secretary of State).

The enforcement powers (7e) will help to ensure the effectiveness of duties imposed on private providers of care.

Costs

The following section will provide an indication of the costs that may materialise if these powers are exercised, or following the introduction of regulations. Overall, it is not possible to provide an equivalent annual net direct cost to business (EANDCB) figure for these proposals yet as the details of how the proposals will be used and any exemptions or regulations have not been developed. However, the process would be kept under review as information needs develop and an EANDCB and SaMBA will be provided as part of an impact assessment once the details of how the powers will be used are finalised.

To provide an indication of potential impact on business, the section is split to discuss each proposal (7a-e) in turn, although the statistics in care market size and the number of small and micro businesses discussed in reference to proposal 7a will be useful context for other sections.

Proposal 7a

As at June 2022, there are 14,754 CQC registered care homes in the social care market registered with a voluntary capacity tracker administered by NHS England to support the Covid-19 response, of which 99% have provided data at least once and 81% have provided data in the last 7 days. . 10,027 CQC registered domiciliary care providers are also currently registered with the capacity tracker following the transition of the home care survey from CQC in December 2020. Of these, 96% have provided data at least once and 70% have provided data updates in the last 7 days. In terms of proposal 7a, the details of the data which may be collected on a mandatory basis using these powers are yet to be determined, and therefore a comprehensive assessment of future potential burdens placed on providers cannot yet be undertaken.

If, for example, the power were exercised and a requirement was placed on care providers (who may be private businesses) to provide information that they do not already collect, this may lead to an impact on the provider in terms of administrative costs. These costs may include; staff time to collect the data; costs to introduce and maintain IT to store data securely, including security software; familiarisation and training costs in terms of proper handling of data and use of new software for staff, and, staff time to collate and send the data in the required format.

Although the paragraph above gives an indication of potential costs, it is the intention to minimise any additional burden on (public or private) providers of care where possible. This is underlined by the intention to follow the below principles when determining how the powers will be used:

- Data will be collected once and shared with those who need it, to avoid national government and Local Authorities collecting the same data separately from care providers;
- Feedback will be sought from provider group representatives prior to finalising the details of any data collection;
- Frequency of data collection will be the minimum needed to meet data needs. During the pandemic the voluntary capacity tracker data collection was daily for some data items, however, it is likely that in a non-emergency situation most data will be needed monthly or less frequently.
- The collection of very granular data, such as detailed data on individual care users, will be kept to a minimum where such data are not held in digital format and therefore would present a significant burden on providers to submit manually.

- If individual level data are being collected, providers will not be expected to bear the burden of anonymising or pseudo-anonymising such data, rather this will be taken into account when identifying an appropriate data collection mechanism.

Any costs that may materialise cannot yet be quantified as details of how the enabling powers may be used have not been decided. At that point, an impact assessment and EANDCB will be produced as appropriate.

Defining small and micro providers as having fewer than 50 employees and using a ratio of 1.5 employees per bed³⁴, small and micro care providers can be defined as those having fewer than 33 beds in total. We define a provider using the provider ID field in the CQC care directory, and count brands as a single provider even if they have multiple provider IDs. As at June 2022 there are 3,572 such care home providers out of 6,370 in England, although they only represent 63,982 beds out of an England total of 457,403. However, some will not in fact be small and micro providers if they have a higher staffing ratio than 1.5 or if they have activity in other markets. It should be noted that the smaller providers are disproportionately likely to serve younger adults, where self-funder numbers are substantially lower, so will be less affected by the reforms. These numbers therefore represent an upper bound of the number of small and micro businesses. Therefore, small and micro businesses will not generally be exempt from the proposals because we need to collect data from across the whole sector in order to get the full picture of the social care market. For example, excluding small providers would significantly impact DHSCs ability to collect data on younger adult care homes, which tend to be smaller. It is not currently possible to state whether small and micro business will be disproportionately affected by the legislation until details of what data will be collected. It is plausible that small providers with little IT infrastructure or few staff may face a disproportionately high cost to collecting and storing additional data (as for example, increased workload on a small organisational workforce will have a greater proportional effect on resource constraints than on a large organisation). It is the intention that any additional costs will be minimised when exercising these powers, and that a small and micro business assessment (SaMBA) will be completed as appropriate and due consideration given to the need for exemptions.

Proposal 7b

The requirement for private providers to provide anonymous information is not intended to impose significant additional burdens on organisations to collect information; the intention is to enable organisations to require other organisations to provide anonymous information they already hold. Therefore, there are likely to be no significant additional burdens from collecting data that is not already held. The clause expressly provides that organisations cannot be required to process information to render it into a form in which it must be provided. This means that organisations will only be required to share information if they already hold it in a form that does not identify an individual, or, enable the identity of an individual to be ascertained. Any data held that is not in this form will not be subject to the requirement. Therefore, it is intended that providers will not be subject to any costs processing existing information to render it anonymous.

There may be an administrative cost on organisations required to provide information; for example, staff time taken to send the data across to the relevant public body. The Act

³⁴ Skills for care report 680,000 residential staff. Table 6, <https://www.skillsforcare.org.uk/adult-social-care-workforce-data/Workforce-intelligence/documents/Size-of-the-adult-social-care-sector/Size-and-Structure-2020.pdf>. CQC data for April 2021 show 458,955 registered care home beds, see the care directory with filters at <https://www.cqc.org.uk/about-us/transparency/using-cqc-data>.

includes a power to make regulations to provide for exceptions to be introduced such as where the data is commercially sensitive. We do not intend that the power to require information will be commenced until the regulations are in place and we will assess potential burden on providers and how we can mitigate these as part of the development of the regulations. Until the exemptions have been finalised, it is not possible to give a comprehensive assessment on the scale of impacts on businesses. In particular, this is because the number of private providers affected by them is not yet known. As an indication of the number of businesses potentially affected, one may refer to the social care market analysis presented in 7a. An EANDCB and SaMBA will be produced alongside the regulations as part of an impact assessment as appropriate to fully assess the impacts of the proposals, including on private providers who have not been captured by the market size statistics above.

Proposal 7c

In relation to 7c(iii) private health care providers are already required by the Competition and Markets Authority to provide information on the services they provide to the Private Healthcare Information Network (PHIN). NHS Digital is currently working with PHIN to ensure a common set of standards for data collections, performance measurement methodologies and reporting systems across NHS and private healthcare. The provisions in the Act will support this work, a key strand of which is to identify where current and future burdens (for instance providers having to provide different sets of information for different services) can be reduced.

However, as with proposal 7a above, if the power was exercised and a requirement was placed on private healthcare providers to provide information that they do not already collect, this may lead to an impact on the provider in terms of administrative costs. These costs may include; staff time to collect the data; familiarisation and training costs in terms of proper handling of data, and, staff time to collate and send the data in the required format. If these powers were to be exercised, then an assessment of the potential costs and benefits, including an EANDCB and SaMBA would be completed as appropriate. As mentioned, when discussing proposal 7a, smaller providers may be disproportionately affected, which would be considered, along with any exceptions, if these powers were exercised.

These are enabling powers and it is not therefore possible to quantify what, if any, burden may be imposed on private healthcare providers. The potential additional burden on private organisations will be reviewed as part of the development of any directions to NHS Digital made under section 254 of the Health and Social Care Act 2012, which would support NHS Digital to require information from private providers.

Administrative costs to NHS Digital associated with the changes we are making to its functions and powers (points 7c(i) and (ii)) are expected to be limited as the new legislation is intended to provide clarity on NHS Digital's key duties and the purposes for which it may share information rather than to impose additional requirements on it.

Proposal 7d

This proposal mandates compliance with standards for the processing of information (including how it is collected and stored) by the health and adult social care sector including providers. Information standards are already applied to public health and adult social care bodies and to providers acting pursuant to arrangements with such bodies and they are expected to comply with them. Compliant providers should therefore have budgeted for the cost of compliance with information standards. However, the proposed legislation provides that information standards may also be applied to private providers, and enables them to be enforced by financial penalties, and they may therefore incur new costs. These costs on private providers of healthcare may be in terms of the costs of processing data in accordance with the standards.

Costs of processing data in line with information standards may include increasing staff time and updating IT systems to process data in the correct format, ensuring the data is securely stored, and available to the appropriate recipients. It is not possible to quantify the scale of these costs as the scope of these requirements have not yet been finalised. If these powers were to be exercised, then an assessment of the potential costs and benefits, including an EANDCB and SaMBA would be completed as appropriate. As mentioned when discussing proposal 7a, smaller providers may be disproportionately affected, which would be considered, along with any exceptions if these powers were exercised.

Regulations will set out the procedure for preparing and publishing information standards and this is intended to ensure that new standards set are reasonable and achievable and it is expected that providers will factor in the cost of meeting them.

Proposal 7e

This provision enables the Secretary of State to make regulations to enable the imposition of a financial penalty on private providers who, without reasonable excuse, fail to comply with an information standard (provision 7d) or who fail to comply with a requirement to provide information under provisions 7a, 7b, 7c(iii) or who provide false or misleading information under those provisions.

This may impose costs on businesses, although a robust figure as to what this cost may be is not possible to estimate as details of these penalties, if imposed, would be finalised at secondary legislation stage. Furthermore, compliance is difficult to estimate, in particular, without knowing full and final details of the data requirements.

Benefits

Benefits from all proposals are indirect and, except 7b, depend on the actions of NHS Digital and/or the Secretary of State. Nonetheless, clarifying that information may be disseminated for wider purposes which would include the wider health and adult social care system will enable NHS Digital to make better use of data it currently collects. On the other hand, implementing power 7a will strengthen the Secretary of State's oversight of social care provision, ensuring that the right level of capacity and support is available to ensure service continuity. Over time it should contribute to parity of information available from health and care providers. In addition, 7c(iii) will support improved safety and quality across private and NHS health services.

Improving the enforceability of standards (7d) will strengthen the negotiating position of officials dealing with non-compliant health and adult social care providers.

Risks and mitigations

The primary risk identified for this proposal is that, at the present stage, there are no processes in the legislation which will require new requests for information to be evaluated, or for the overall burden on NHS Digital and health or social care providers to be periodically reported and reviewed. The Department will consult with the Capacity Tracker Data Advisory Group (CT DAG) on all data changes as we have throughout the pandemic and continue to.

These data provisions, which would be enforceable, may be seen as risking the creation of onerous legal duties on health and care system providers. We will seek to consider and mitigate this risk including as part of the development of regulations under these powers, which are subject to the affirmative procedure in Parliament.

For information standards (7d), it is expected that this risk will be mitigated by a thorough statutory procedure for preparing and publishing new standards, based on the current procedure. The new procedure is intended to include consultation with stakeholders, and to ensure that information standards are proportionate and fit for purpose. A robust, regular review process will also be implemented to ensure that information standards are kept up to date and there will also be a waiver system that will allow providers to apply for a temporary or long-term waiver from complying with an information standard in circumstances set out by the Secretary of State.

8. Foundation Trusts capital spend limit

Policy summary

This provision will give NHS England a power to set an annual capital expenditure limit for an individual, named NHS foundation trust (FT). One of the barriers to developing a more collaborative approach to planning capital investment is that, whilst Parliament approves an annual financial envelope for capital expenditure across the Department of Health and Social Care and the NHS, and NHS England set capital spending limits on individual NHS Trusts, pre-Act there were no mechanisms to do the same for NHS foundation trusts

NHS England and NHS Improvement previously explored voluntary approaches to address the need for capital controls across providers, but given the lack of proportionate legal mechanisms to require solvent NHS foundation trusts to adhere, there was a risk that these would be unsuccessful in protecting the NHS's overall capital limits. The Act therefore provides a power for NHS England to set, by order, capital expenditure limits on NHS foundation trusts. **It is expected that this power will be used only in cases where there is a clear risk that FT spending plans could breach their local system capital envelope, and as a last resort, for a specified period, for individual FTs.** NHS England is not expected to use it to impose capital expenditure limits on the vast majority of FTs.

This provision does not create a direct cost to the system as a whole, as the capital spending envelope remains constant across the NHS. It will also be supported by the requirement that each ICB and partner NHS trusts/FT develop a Joint Capital Resource Use Plan to target its capital spend strategically across the system. This is also expected to result in a more collaborative approach to capital spending.

Costs

As this is an enabling power it is not expected that there will be any direct costs from the provision. It should be acknowledged that, if the power were to be exercised, imposing a capital limit changes the freedom which FTs were previously given to make capital investment decisions.

Benefits

As part of the Long-Term Plan's 'Five Tests', the NHS outlined a commitment that the NHS will make better use of capital investment and its existing assets to drive transformation. Part of the justification for this test is the urgent need to invest in the buildings and facilities of the NHS to meet the demands of a modern health service. This provision will attempt to create balance between unpredictable capital costs; the high-priority spending which also needs to be addressed; and lower-priority capital projects which require longer-term planning to be met.

Applying the control would mean that the FT investment foregone is available to other NHS organisations with a fairer distribution of capital to enable investments with higher need and achieving greater benefits to staff and patients.

Risks and mitigations

FTs may in future incur costs to secure commercial loans, which they may be unable to spend due to the imposition of a capital limit.

A further risk is that beneficial capital investment in the Foundation Trust sector, including reinvesting their own capital, may be prevented or disincentivised. This could take the form of deterring FTs from pursuing innovative approaches to estates redevelopment.

A further example is if a FT is faced with a potential capital limit in the following year, the FT may delay starting a project in the current year because any costs running into the following year (whether because it's a long term project or unforeseen delays) could breach the capital limit. A potential cost of this would be to delay getting the benefits for a further year, likely cost increases due to inflation, or, backlog maintenance issue getting progressively worse so that more investment is required to fix them.

These will need to be mitigated by clear expectations on how NHS organisations and systems should approach their capital plans in the long-term and assign the limited capital funds to where they can achieve the greatest benefits to staff and patients. The Department in the 2021 Spending Review has received a multiyear capital settlement and this remains the aim going forward to provide more certainty on future resources and support better long-term planning.

9. Competition

Policy summary

The provisions in this group intend to change the roles in respect of competition of the Competition and Markets Authority (CMA) and the post-merger NHS England, to create a more nuanced approach to certain NHS transactions that gives greater weight to collaboration (while still recognising the value of competition).

The provisions in this section are:

- a. **The CMA's function to review mergers involving solely NHS foundation trusts or NHS foundation trusts and NHS Trusts should be removed.** Instead the merged NHS England will continue to review proposed transactions, including mergers or acquisitions, to ensure there are clear patient benefits.
- b. **The competition powers and duties which prior to the Act sat with Monitor (NHS Improvement) should be removed.**
- c. **The requirement to refer contested license conditions or Tariff provisions to the CMA, which prior to the Act applied to NHS Improvement, should be removed,** along with the provisions that prohibit NHS Improvement from proceeding with a National Tariff publication if the proportion of relevant objections reach a certain threshold.

Pre-Act legislation required Trusts that were considering a merger between themselves to engage with the CMA's merger regime, if at least one is a Foundation Trust. This can be a time-consuming and complex process with significant resource requirements. In practice, the CMA has reviewed about one NHS merger per year since 2013, although it is likely that

increased collaboration in the NHS may lead to more mergers. It should also be noted that the CMA has only blocked one merger (in 2013), and that this merger was subsequently allowed. It is also unlikely the CMA would block any mergers that were presented correctly, and which focused on demonstrating the patient benefits that would accrue as the result of such a merger³⁵. The CMA is supportive of this change in legislation³⁶.

Powers to enforce the Competition Act 1998 and Enterprise Act 2002 in relation to the provision of healthcare services in England ('concurrent powers') were conferred on NHS Improvement (as Monitor) by the Health and Social Care Act 2012. The Act also gave Monitor a general duty to prevent anticompetitive behaviour where it was not seen to be in the interest of patients.

As explained by the Health and Social Care Committee in their 2018 Integrated Care report, "[The] then Secretary of State for Health, told our predecessor Committee in 2011: *What we are doing, through amendments to the legislation, is to make it absolutely clear that integration around the needs of patients trumps other issues, including the application of competition rules.* However, despite that reassurance, reforms to extend the NHS internal market, including the role of competition, have impeded rather than supported services to integrate." The policies in the Health and Care Act give a renewed focus on encouraging greater integration between care providers, and therefore the retention of concurrent powers to enforce competition law, whilst simultaneously promoting integration, would create mixed messages for providers, as competition is perceived as conflicting with a drive towards integration. The removal of the concurrent powers will signal to providers that collaboration and quality should be the organising principles that underpin the planning and delivery of NHS care. Competition will still play an important role in driving improvement in NHS-funded healthcare, for example, through competitive procurement exercises and patient choice. The removal of the concurrent competition powers that were held by NHSI is to reflect NHS England's primary role to support improvement in the quality of care and use of NHS resources, rather than as an economic or competition regulator.

The Health and Social Care Act 2012 gave the CMA functions which allowed it to conduct regulatory appeals and redeterminations in relation to price controls or terms of licences, although it is not clear that it has the expertise and insight into NHS services to be the appropriate holder of this role. Removing the relevant CMA powers will ensure that decisions are made in the interests of the NHS as a whole will and minimise the risk of delays to licensing decisions and to National Tariff publications.

Costs

Costs will depend on any future change in the propensity to judicially review contested licence conditions which can currently be referred to the CMA (9c). Any benefits associated with the duty to prevent anticompetitive behaviour will also be forgone.

Benefits

The benefit of these provisions will be to enable integrated care across foundation trusts and to reduce the administrative cost of any future mergers, by reducing the bureaucracy associated with CMA involvement in merger reviews (9a). It will also encourage collaboration between providers (9b) and increase the autonomy of the NHS in licensing. The provisions may also have the benefit of removing administrative burden to Trusts of complying with processes that are not designed for or suited to the health system.

³⁵ Competition and Markets Authority, 'CMA's response to the Health and Social Care Committee', 2019. [Online]. Available: <https://www.gov.uk/government/publications/cmas-response-to-the-health-and-social-care-committee>

³⁶ Ibid.

Risks and mitigations

There is a risk that removing the CMA's role in assessing mergers will lead to reduced oversight on the rationale for those mergers. For example, there is a small risk that mergers go ahead which are not in the best interest of patients. In addition, there may also be a risk that not having a regulator independent of the health sector will lead to sub-optimal economic outcomes from mergers. It may be that the economic considerations of competition, and the links to wider national competition policy are to some extent lost. However, as previously mentioned, in practice the CMA has only blocked one merger (in 2013), and that this merger was subsequently allowed. It is also unlikely the CMA would block any mergers that were presented correctly, and which focused on demonstrating the patient benefits that would accrue as the result of such a merger³⁷. The key mitigation to this is that NHS England will continue to review and sign-off mergers, whilst the Secretary of State will now sign off all mergers (not just those including an NHS Trust).

10. Provider selection and Choice

Policy summary

This set of provisions makes changes to legislation to enable new regulations to be made which provide decision-making bodies (including Integrated Care Boards, NHS England, NHS trusts, and NHS foundation trusts, local authorities and combined authorities) with flexibility when deciding the circumstances in which competitive tendering should be used to arrange services. The intention is to introduce regulations so that decision-making bodies would be subject to a new provider selection regime when procuring health care services which would encourage them to do so in a way that secured the best outcomes for patients and the taxpayer. An impact assessment detailing the costs and benefits of the Provider Selection Regime will be published in due course alongside the regulations.

These measures also include provisions to ensure that patient choice is maintained and strengthened where appropriate. This is intended to mitigate any risk to patient choice rights or protections in legislation affected by the set of changes on procurement.

The provisions in this section are to:

- a. revoke the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (PPCCR 2013), and repeal section 75 of the Health and Social Care Act 2012;
- b. create an enabling power to remove arrangements between NHS commissioners and providers of healthcare services from the scope of the Public Contracts Regulations 2015 (PCR 2015);
- c. create a power that allows for the introduction of a new NHS provider selection regime via regulations – informed by public consultation and supported by statutory guidance – which sets out how decision-making bodies should secure the best outcomes for patients and the taxpayer; and
- d. introduce legislative changes to preserve and strengthen patient choice; under the new model, bodies that arrange NHS Services will be required to protect, promote and facilitate the right of patients to make choices with respect to services or treatment.

³⁷ Competition and Markets Authority, 'CMA's response to the Health and Social Care Committee', 2019. [Online]. Available from: <https://www.gov.uk/government/publications/cmas-response-to-the-health-and-social-care-committee>

There was a high level of support for reforming the current procurement rules when asked as part of the NHS consultation³⁸. Of the 578 respondents to the question “Do you agree with our proposals to free up procurement rules including revoking section 75 of the Health and Social Care Act 2012 and giving decision-making bodies more freedom to determine when a procurement process is needed, subject to a new best value test?”, 75% of respondents either Agreed or Strongly Agreed. This provision acts on the preferences of key stakeholders to improve the provider selection arrangements in the NHS.

The impact of these changes would be to streamline and simplify the current rules which involve compliance with two different sets of requirements – the PCR 2015 and the PCCR (2013). NHS commissioning contracts generally fall under the light-touch regime in the PCRs, meaning that they have greater flexibility in how they are procured. However, the PCRs are associated with a significant and/or perceived risk of legal challenge if certain services are not advertised for tender. This can disincentivise attempts to reconfigure services towards more integrated models, even when benefits to patients and to service delivery can be shown.

A key rationale for intervention is that competitive tendering processes can be costly and in some cases not running a competitive tender would result in the same outcome, but without the added costs of running the tendering exercise. When running or partaking in a competitive tendering process, costs are incurred both by commissioners (in writing specifications and running procurement processes themselves) and by potential providers of care (all of whom spend considerable time working up bids if they decide to compete). These providers of health and care may include non-NHS bodies (including independent, voluntary and Civil Society Organisations), who accounted for 10.8% of NHSEs RDEL spend in 2019/20 (or £14.43bn)³⁹. A 2016 report into NHS commissioning by the Policy Research Unit in Health and Social Care Systems and Commissioning stated:

“All the commissioners [who took part in the research] noted, nevertheless, that a large call on resources was needed in order to carry out a procurement process, and that it was not possible to undertake many of these exercises, due to the limits on their resources. The process was time consuming and cumbersome.”⁴⁰

PRUComm (2016) highlighted several different areas where costs lie in the current system based on interviews with several CCGs and providers. In summary, commissioners and providers found that tendering was very resource intensive⁴¹, which is explored in further detail in the cost section below. The provisions enable new regulations to be made which clarify the discretion decision-making bodies have in deciding on the circumstances in which they should use competitive tendering processes to arrange services. In turn, this may remove the need to undertake procurement exercises where competitive tendering has no added value, and in turn provide cost savings. A full assessment of the EANDCB and the impact on small and micro businesses will be undertaken at secondary legislation stage when the details of the provider selection regime are finalised. The impact of the provisions once implemented will be fully evaluated as part of the post implementation review.

³⁸ NHS England, The NHS’s recommendations to Government and Parliament for an NHS Bill, Annex 1: Implementing the NHS Long Term Plan: Public Engagement on Proposals for Possible Changes to Legislation, 2019. [Online]. Available from: [PowerPoint Presentation \(england.nhs.uk\)](https://www.nhs.uk/longtermplan/annex-1-recommendations-to-government-and-parliament-for-an-nhs-bill)

³⁹ Department of Health and Social Care Annual Report and Accounts 2019-20, p220 [Department of Health \(publishing.service.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/424242/2019-20-annual-report-and-accounts.pdf)

⁴⁰ PRUComm, Commissioning through competition and cooperation, (2016). P101. [Online]. Available from: <https://prucomm.ac.uk/2016/06/17/commissioning-through-competition-and-cooperation/>

⁴¹ PRUComm, Commissioning through competition and cooperation, (2016). P1436. [Online]. Available from: <https://prucomm.ac.uk/2016/06/17/commissioning-through-competition-and-cooperation/>

DHSC, in collaboration with NHSE and cross-government stakeholders, are currently developing, informed by the recent consultation, a new provider selection regime which will give decision making bodies more flexibility in choosing how to arrange services, factoring in issues like service sustainability and social value. The scope of the new procurement regime is currently being developed and therefore, the uncertainty over the impacts of a provision is too great to provide a meaningful Equivalent Annual Net Direct Cost to Business (EANDCB) or SaMBA at this stage.

The scope of the regime which determines what decision-making bodies are impacted by this new regime, as well as what goods and services are affected, has not yet been finalised. This means that the number of providers or the number of contracts which will be affected by the regime also cannot be accurately stated at this stage. Further analysis of the number of providers affected by the finalised provider selection regime, and the potential impacts on those (public and private) providers and businesses (including those which are small and micro) is ongoing and DHSC will publish a full assessment of the EANDCB and SaMBA at secondary legislation stage. Any exemption for small or micro businesses from the regulations would be investigated during the development of secondary legislation in conjunction with partners across government.

Costs

The policy summary outlined a rationale for intervention based on the current procurement rules leading to high costs to commissioners and providers. These costs are typically in terms of time and resource of staff, but also opportunity costs as those resources may be better used elsewhere.

A specific unit cost for running or taking part in tendering exercises is difficult to calculate as these costs will differ based on the nature of the procurement. For example, a CCG respondent to PRUComms initial 2016 study on NHS health and care commissioning reported that a smaller competitive tendering process “took 18 months to complete and cost around £250,000 spent on salaries and legal advice”⁴². Another CCG who took part in PRUComms subsequent 2017 research reported that a recent long and complex competitive procurement process cost millions of pounds⁴³. This demonstrates there is a wide range in potential costs to commissioners for running competitive tendering processes. For providers, including private businesses, costs of bidding as part of competitive tendering process have also been reported. One Community Healthcare Services provider who took part in PRUComms 2017 research suggested that there is an administrative cost of undertaking bids in terms of assessing whether to bid, constructing bids and contracts, and completing presentations. This can come to tens of thousands of pounds per tender⁴⁴. This administrative cost may include the time taken to attend and understand the nuances of the market engagement exercises run by commissioners, and staff time in drawing up and submitting bids.

The paragraph above demonstrates the potential costs of competitive tendering to (both NHS and non-NHS) providers and commissioners. These provisions therefore enable DHSC to introduce a new provider selection regime which gives decision-making bodies flexibility on when to undertake competitive tendering processes and in doing so may save on costs associated with competitive tendering. This aims to remove the requirement to tender services where there is no clear benefit in doing so, particularly where there is a single preferred provider when assessed against the success criteria of the regime (which may

⁴² PRUComm, Commissioning through competition and cooperation, (2016). P89. [Online]. Available from: <https://prucomm.ac.uk/2016/06/17/commissioning-through-competition-and-cooperation/>

⁴³ PRUComm, Next Steps in Commissioning through Competition and Cooperation (2016-2017), 2017, p57. [Online]. Available from: [CompCoop2-addit-report-dec-2017-final-amended.pdf \(prucomm.ac.uk\)](https://prucomm.ac.uk/2017/12/14/next-steps-in-commissioning-through-competition-and-cooperation/)

⁴⁴ PRUComm, Next Steps in Commissioning through Competition and Cooperation (2016-2017), 2017, p79,80. [Online]. Available from: [CompCoop2-addit-report-dec-2017-final-amended.pdf \(prucomm.ac.uk\)](https://prucomm.ac.uk/2017/12/14/next-steps-in-commissioning-through-competition-and-cooperation/)

often be the incumbent provider). Additionally, this flexibility ought to remove unnecessary bureaucracy which disrupts attempts at designing and delivering a well-coordinated and integrated healthcare system so that services can be commissioned in a way which best promotes the interests of patients, the taxpayer, and the population.

Any costs to NHS and non-NHS providers are likely to materialise once a new provider selection regime is put into place following secondary legislation. The primary legislation itself does not impose any costs, but it does provide powers which give government the ability to create a new provider selection regime, which in turn may impact upon costs to business.

At this point in policy development for the Provider Selection Regime (PSR), DHSC do not envisage significant costs to businesses beyond those driven by the existing public procurement regime. The proposals for the PSR are still under development and the proposals and scenarios outlined here are indicative only. They are, however, based on proposals which NHS England consulted on from February to April 2021 and which DHSC consulted on further detail between February and March 2022. Now that the Bill (Act) has received Royal Assent, DHSC are able to proceed with plans to introduce the PSR using these enabling powers, although details of this are still being developed.

Current legislation governing the procurement of healthcare services is interpreted as requiring a competitive tendering process to procure most contracts. This applies for the procurement of new contracts and the retendering of contracts. Under the PSR, competitive tendering will become one pathway of three. Another pathway towards procurement for healthcare services will be rolling over a contract where a service continues to be provided successfully and retendering would cause undue disruption to services and integration. The final pathway is to allow contract awards to a new provider without competitive tendering where a service has changed significantly, or is new, or the incumbent is not providing the service to a sufficient standard, but there is no value in running a competitive tender. This may be because there is not a sufficiently mature market from which to choose providers. Similarly, due to the complexity of the required contract to promote better integration of services there may only be one most suitable provider in a given locality.

When considering costs for businesses of the proposed PSR against the existing regime it is difficult to estimate the likelihood of additional costs for businesses until the PSR is defined, although DHSC will work to ensure such costs are minimised. In the scenario where there is healthy market competition, which should be tested by decision making bodies, then a competitive tendering process will still be used which would come at the same cost to all competitors as under existing tendering competitions. If there is not a market and competitive tendering is not used for procurement in under the PSR, then awarding the contract directly to the existing or only viable provider will come at a much-reduced transactional cost for those businesses whilst enabling commissioners to arrange services so that they are better coordinated and more joined-up. We expect this to lead to better allocation of resources without incurring additional costs for businesses. Three illustrative scenarios are provided below.

Scenario 1 – Competitive Tender

An ICB wishes to procure diagnostic services (e.g. blood testing) for its local area and there are several potential choices of provider who may deliver this service effectively. The ICB decides to run a competitive tender for this service. The tender is underpinned by the success criteria as given in PSR regulations and guidance to determine the most suitable provider. This means businesses as well as statutory providers could bid for the contract. Bidders incur in costs when preparing their bids as businesses currently do at the moment when participating in competitive tendering ran by Clinical Commissioning Groups or NHS

Trusts now. Therefore, no additional costs driven by policy change are anticipated for businesses in this scenario.

Scenario 2 – Single Viable Provider

An Integrated Care Board (ICB) and local authority working together wish to procure a service to provide sexual health clinics in a rural locality. Due to the remote nature of the area and a lack of independent providers, the only provider who is able to deliver the service is a local NHS Trust. The ICB and local authority decide to award the contract to this provider. This decision is guided by the criteria set out by the regulations and statutory guidance for the PSR. When considering costs for businesses and decision making bodies, this process would arguably save businesses unnecessary costs which may have occurred due to a competitive tendering process being pursued in order to mitigate legal risk of a claim against the decision making body under the existing regime. Therefore, no additional costs driven by policy change are anticipated for businesses in this scenario.

Scenario 3 – Contract Rollover

A Local Authority (LA) manages a contract with an independent provider who works closely with the LA and several small local providers to deliver integrated mental health services. The provider has excellent relationships with all the relevant providers and is considered to be invaluable in integrating services to give service users fluid end to end user journeys which increases the effectiveness of the service in delivering high quality outcomes for patients. The LA assesses that retendering this contract would have a high chance of diminishing the relationships between providers and could lead to disrupted services for service users with adverse outcomes for patient health. As such, in the PSR the Local Authority could allow the contract to continue without retendering. When considering costs for businesses, this process would arguably save businesses unnecessary costs which may have occurred due to a competitive tendering process being pursued in order to mitigate legal risk of a claim against the decision making body under the existing regime. While there is a potential income loss for those businesses who could have won the contract had an open procedure happened, no significant additional costs driven by policy change are anticipated for businesses in this scenario.

We are continuing to develop proposals for the PSR including mechanisms for transparency, scrutiny, and remedy. Further information on the final form of the PSR will be detailed in secondary legislation (regulations) and in statutory guidance as stated in the Health and Care Act. NHS England consulted on proposals for the PSR between February and April 2021 and DHSC then consulted on more detailed questions to help develop the regulations and guidance between February and March 2022. An accompanying impact assessment will also be published in due course.

The central requirement of the proposed new regime is that arrangements for the delivery of NHS services must be made in a transparent way, in the best interests of patients, taxpayers and the population. Competitive tendering will allow decision making bodies to test the market when this provides an opportunity to add value for patients, taxpayers, and the population without generating adverse impacts (e.g. through service disruption or loss of integration between key providers). This in turn will provide businesses with opportunities to enter the market and work alongside decision making bodies to contribute to these objectives. Depending on the design of the new regime, there may be a risk in some instances that removing requirements could lead to the economically optimal option not being identified, as for example there may be reduced opportunities for market entry by providers (which may also be a cost of lost revenue to that provider). However, to mitigate this risk, it is anticipated that competitive tendering will be used unless there is a limited market for a service or a contract is rolled over to preserve a well-functioning service. Where

there is a limited market for a service, decision making bodies will have the flexibility to award contracts without competitive tendering which would (if undertaken) not realistically offer sincere opportunities other than to the single viable provider. Where a contract is rolled over to preserve a well-functioning service and wider integration, this is expected to deliver benefits for patients, taxpayers, and the population above and beyond what can be delivered through fragmented services.

Furthermore, there is a possibility of increased costs stemming from a change in the price of health and care services. If a reduction in competitive tendering leads to the provider sector displaying monopolistic behaviour, the increase in market power could lead to a rise in costs of commissioned services. In line with Better Regulation guidance, a competition assessment will be completed once the details of the provider selection regime are finalised as part of secondary legislation.

It is not anticipated that there will be any additional costs associated with maintaining the current patient choice rights following changes to the procurement rules.

Benefits

These provisions remove barriers to integrating care at scale, which may give rise to patient and efficiency benefits, by removing the barriers created by the current framework. The policy position is based on strong support from within the NHS, delivering on a conclusion of the Long Term Plan that the removal of non-value-adding transactional processes for the procurement of services will help the NHS deliver better care and better value. Ultimately, the savings that could be achieved from the changes proposed will depend on how effectively NHS bodies and their partners are able to improve arrangement of their services. As mentioned in the costs section, it is not straightforward to quantify savings generated of these changes in terms of reduced administration costs because the scope of the regime has not yet been finalised.

PRUComm in 2016 reported that in some cases, competition was seen as a too confrontational form of commissioning which risked provider and commissioner relationships. Conversely, a respondent to PRUComms 2016 report stated that “*Competition remained an important lever for commissioning provided it was not enforced top down but left within the local decision making remit.*”⁴⁵ These provisions therefore support the intention to introduce an improved provider selection regime by removing the bureaucracy associated with mandated competitive tendering and by giving the flexibility to use competitive tendering processes where appropriate. This is in order to remove the requirement to undertake competitive tendering which does not generate additional value to patients or the taxpayer. This may reduce costs for both decision-making bodies and providers in terms of reduced time and resources completing bids, whilst serving the best interests of patients, taxpayers and the population through more integrated services.

Finally, under the current system, some commissioners have said that in order to minimise the risk of legal challenge, they put contracts out to tender even when this is unnecessary, or, go to disproportionate effort to avoid going to tender. A new provider selection regime which offers flexibility to decision-making bodies may reduce the likelihood of service disruption caused by the current procurement process.

Risks and mitigations

The new provider selection regime will require decision-making bodies to continue to seek value and act in the interests of taxpayers; and will contain appropriate protections to ensure

⁴⁵ PRUComm, Commissioning through competition and cooperation, (2016). P101. [Online]. Available from: <https://prucomm.ac.uk/2016/06/17/commissioning-through-competition-and-cooperation/>

decisions can be justified. This will alleviate the possibility of the new regime creating ambiguity in how decision-making bodies ensure proper use of public money.

DHSC are continuing to work with partners across Government in the development of the PSR and the relevant secondary legislation. This is intended to ensure that the risks and benefits of varying policy options are well understood and that the regime is clear and compatible with wider procurement regimes.

The regime will also enable decision-making bodies to address poor provider performance by reviewing contracts against the success criteria set out in the regime. This will be alongside existing measures for challenging poor performance available through NHS England, Care Quality Commission (CQC) inspections and ICB management. The regime will give decision-making bodies scope to take into account poor performance when deciding whether to make new arrangements. The Health and Social Care Committee has expressed a concern⁴⁶ that the absence of competitive tendering could lead to the provider sector displaying monopolistic behaviour which is detrimental to health and care services. Qualitative research on NHS commissioning post-2012 describes “Independent providers [in the study] were wary of the turn towards cooperative mechanisms in commissioning services as it would decrease their opportunities for market entry. [...] Private for-profit providers continued to be critical of how competition has been applied in the NHS”⁴⁷. Continuing effective contract management will be necessary to minimise this risk.

The provisions do not of themselves affect the balance of type of providers in the health and care system. The new regime will give decision-making bodies more flexibility in choosing how to arrange services, factoring in issues like service sustainability and social value, which will give them the ability to plan and arrange services in ways which helps to keep certain services viable. The new regime will also ensure that decision-making bodies seek innovation and consider the impact of their commissioning decisions on the viability of the market, which will mitigate the risk of smaller providers from the independent sector being denied the opportunity to provide services.

The requirements on decision-making bodies and providers to provide a choice of services are also not affected by the provisions. Patient choice rights will ultimately be protected through this package, and patients will continue to have choice of provider via the existing Any Qualified Provider⁴⁸ certification process.

In order to avoid difficulties in decision-making bodies and providers understanding and adhering to the new regime, the changes will be developed in conjunction with the sector, building on the experience of the current procurement regimes. The provisions should ultimately represent an improvement on the current, overlapping PPCCR and PCR regimes.

A risk is also that the net effect of the provisions on the propensity for legal challenge is unclear. On the one hand, the new provider selection regime is intended to simplify the current processes, which ought to reduce the propensity for legal challenge. On the other hand, removing the role of NHS England in commissioner/provider disputes may increase the likelihood for providers to go straight to judicial review. NHS England and DHSC are continuing to explore options for dispute resolution as part of the PSR.

International trade

⁴⁶ Health and Social Care Committee, ‘NHS Long-term Plan: legislative proposals’, 2019, <https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/2000/2000.pdf>

⁴⁷ Pauline Allen et al, *Commissioning Healthcare in England*, (2020), p99.

⁴⁸ See https://webarchive.nationalarchives.gov.uk/20130104211353/http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_125442

The UK has always protected its right to choose how we deliver NHS health and care services in trade agreements and we will continue to do so. The procurement of the UK's public services, including NHS healthcare services, are protected in the trade agreements to which the UK is a party by appropriate exemptions and exclusions to ensure we retain our choice to decide how we deliver these services and the standards suppliers must meet. The UK will continue to ensure that the same rigorous protections are included in future trade agreements.

The provider selection regime is being developed to provide the NHS and local authorities with the tools to deliver better value for patients, taxpayers, and the population. As such, this may cause some divergence between UK rules set out under the PSR and rules under the EU system. Depending on the structure of the new regime, this has the potential to impact international trade and investment, but it is currently not possible to estimate how much given the use of the power is not finalised. In line with Better Regulation Guidance, DHSC are engaging with partners across Government including the Department for International Trade to fully assess any implications for international trade.

11. National Tariff

Policy summary

The set of provisions relating to the National Tariff are intended to update the legislative requirements to reflect and support the drive towards greater integration in healthcare; make adjustments that remove barriers to desired pricing approaches; and simplify and streamline the pricing process.

The provisions will:

- Allow the National Tariff to be renamed as the NHS Payment Scheme
- Allow national prices to be set as a formula rather than a fixed value;
- Provide a power for national prices to be applied only in specified circumstances;
- Allow adjustments to provisions within the NHS Payment Scheme to be made within the NHS Payment Scheme period, subject to consultation on specific provisions alone;
- Remove the power which allows providers to apply to make local modifications to prices;
- Allow the NHS Payment Scheme to include prices for public health services.
-

NHS England has already been working to implement changes to the approach to tariff; the legislation will give increased flexibility and remove the need for complicated workarounds.

Costs

The National Tariff payment system already allows significant flexibility to support new ways of delivering care. Rules on locally determined prices currently allow providers and commissioners to set appropriate local prices and payment approaches, provided they are in the best interest of patients, promote transparency and result from the engagement of commissioners and providers. These provisions will better enable this.

New and more flexible payment models rely on the capability within the system at a local level to implement and design the payment systems to create the right incentives which

support collaboration. This will require support from NHS England to ensure that any new pricing approaches are clear and practically deliverable.

Benefits

New pricing and payment approaches that move beyond simple activity-based prices would support moves towards collaboration and integration within the NHS. Replacing the current practice of reliance on local pricing rules for more innovative and flexible pricing and payment approaches and would give the sector greater guidance and certainty.

Moreover, being able to set full pathway prices for care that cuts across different settings and services is an important aspect for the NHS Payment Scheme to directly influence and enable integrated care.

There is the potential for administrative savings from the introduction of multi-year or multi service contracts between organisations in local areas, and from the reduced administrative burden of responding to multi-year rather than annual tariff consultations. However, it is not clear at present whether there will be a net administrative saving or cost.

Risks and mitigations

There is a risk that the option for part of the NHS Payment Scheme to be changed mid-tariff could result in an increased uncertainty for commissioners and providers. However, as demonstrated by the departure from the National Tariff at the beginning of the Covid-19 response, flexibilities such as these can be helpful and even necessary for the system.⁴⁹ Under usual circumstances, this risk will be mitigated by the duties to consult on changes to the NHS Payment Scheme before they are introduced.

If the NHS Payment Scheme rules are unclear or complex this may lead to some additional work for commissioners and providers to identify relevant activity and assign different prices; it may also limit the information available to independent providers. This may have implications for allocative efficiency. Again, existing duties seek to mitigate these risks: NHS England will continue to consult on tariff provisions and continue to publish a tariff and financial frameworks in collaboration with DHSC.

12. New trusts

Policy summary

This provision ensures that the Secretary of State will continue to have the power to create a new NHS Trust. New trusts could be created to facilitate integration, as well as to ensure the health system is structured to deliver the best outcomes for whole population health and respond to emerging priorities.

Commissioners may apply to the Secretary of State for the creation of new NHS Trusts. This, in turn, enables the Secretary of State to establish new trusts to spearhead delivery of the ICBs' integration goals at place level, through holding and delivering an Integrated Care Provider contract⁵⁰ or similar population-based contract, and in a way that aligns with the delivery architecture of their primary care networks.

⁴⁹ NHS England and NHS Improvement, 'Revised arrangements for NHS contracting and payment during the Covid-19 pandemic', 2020, p 3. [Online]. Available from: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/COVID-19_NHS-contracting-and-payment_26-March.pdf

⁵⁰ One of the available options for systems to enable joined up decision making and integration of services. It will enable commissioners to award a single contract to a provider that is responsible for the integrated provision of general practice, wider NHS and potentially local authority services.

The Secretary of State powers to create a new trust are not limited to the circumstances above. The experience of the Covid-19 pandemic, and the creation of the Nightingale hospitals has demonstrated there may be wider circumstances where it would be beneficial for the Secretary of State to be able to create NHS trusts for a variety of purposes. The Act simply repeals the uncommenced 2012 Health and Social Care Act provisions on abolishing NHS trusts to align with the policy of being able to create new NHS Trusts in the future.

It is the expectation that the power to create new NHS Trusts will be used rarely when not triggered by a local application. A scenario where the Secretary of State would create a new trust against the will of NHS England or the local systems affected is not anticipated. In any circumstance, local engagement would still be expected before a new trust can be created.

Costs

With respect to commissioner applications, this provision has no direct cost. It is intended to not prevent local change, should this be locally desirable. The costs associated with the formation of a new NHS Trust are outside the scope of this impact assessment: it would be for local evaluation by local commissioners in putting together an application to create a new Trust for this purpose, and demonstration of this could be one of the conditions affecting the Secretary of State's decision whether to approve a request for a new NHS Trust.

For the remaining circumstances, costs depend on decisions to create new trusts that have not been taken, and that are not expected to occur often. In any circumstance, local engagement would still be expected before a new trust can be created.

Benefits

We anticipate that this provision would be used to help overcome a local implementation challenge. CCGs have found local delivery partners unwilling to use an existing NHS trust or foundation trust as the Integrated Care Provider contract holder.

In some areas, a strong preference has been expressed by delivery partners, to create a new statutory provider, designed specifically for the purposes of providing a whole population health model and with a bespoke structure that contains the breadth of expertise necessary to deliver a broad contract scope. However, the existing legislative framework does not lend itself to the creation of new statutory providers for this purpose.

Risks and mitigations

It will be for local areas to assess the costs, benefits and risks of any provision to create a new NHS Trust; and this will be tested by NHS England as part of the Integrated Services Assurance Process (ISAP) before a contract is awarded.

There is a risk the power to create new trusts is used more often, or in different circumstances, than anticipated. However, this provision simply clarifies in legislation a power the Secretary of State clearly had before the Health and Social Care Act 2012 was enacted, from which major risks did not materialise. As before, any creation of a new trust will come with an expectation of local engagement, which provides some mitigation.

13. Special Health Authorities Time Limits

Policy summary

This provision would remove the existing automatic requirement for Special Health Authorities created since 2012 to be abolished within three years of being established. The

three-year time limit for Special Health Authorities was introduced in the Health and Social Care Act 2012, to apply to new Special Health Authorities from that point forward. A number of Special Health Authorities were already in existence and so their tenure has been enduring. The time limit was intended to maintain a stable system architecture by ensuring that when a Special Health Authority is required for a specific purpose, it does not continue to exist once that purpose has been met. The legislation allows for the three-year limit to be extended via an order subject to the affirmative parliamentary procedure⁵¹.

One of the intended effects of the time-limit was to prevent the proliferation of Special Health Authorities, and the creation of new authorities has indeed been limited - only one, the NHS Counter Fraud Authority, has been created since the change in legislation and the nature of its remit is such that it has enduring purpose. Special Health Authorities are recognised as a critical part of the arm's-length body landscape and do highly specialised work; this change would place the NHS Counter Fraud Authority on the same footing as the Department's other Special Health Authorities. To give both strategic and operational clarity, it is important to change legislation to ensure that Special Health Authorities do not have a three-year expiry.

Costs

Changing the presumption in law that Special Health Authorities, both new and established after 2012, are a permanent fixture of the health service DHSC, additional costs are not expected, as this was already the established practice.

Benefits

Amendments to legislation will provide continuity of operational delivery, and clarity within the arm's-length body landscape. They will bring some additional reassurance to Special Health Authorities that they are not in legislation as a temporary fixture, and that they have parity with other arm's length bodies. However, these changes are occurring within a new context where the Secretary of State will have a new power to transfer functions to and from arm's-length bodies through secondary legislation.

The legal expiry date means that DHSC must apply for an extension for post-2012 Special Health Authorities at least every three years. By removing the need to reapply for an extension, there will be a small saving of resource on the part of the Civil Service, lawyers and Parliament.

Risks and mitigations

We anticipate limited risks from this policy, it is purely a structural change to bring the one ALB (NHS Counter Fraud Authority) into line with the other Special Health Authorities.

14. Arm's-Length Bodies transfer of functions power

Policy summary

This provision will create a general power in primary legislation for the Secretary of State for Health and Social Care to transfer functions to and from Arm's-Length Bodies (ALBs) and to provide for functions of the Secretary of State that could be delegated to a Special Health Authority, instead to be delegated to a non-departmental public body. Consequential upon this, the Secretary of State will have power to abolish a body if all of that body's functions have been transferred. There will be a specific exception to this for NHS England, providing

⁵¹ See <https://www.legislation.gov.uk/ukpga/2012/7/notes/division/5/1/8/3>

that the Secretary of State may not render it redundant by a transfer of all of its functions to other bodies. This power will allow the Secretary of State to make changes to primary legislation, by using secondary legislation. However, any changes will require further Parliamentary scrutiny and consultation before coming into force.

The existing ALB landscape has remained largely unchanged since the Health and Social Care Act 2012 reforms. As the health service has evolved, this fixed ALB structure has led to a fragmentation of roles between different organisations and has often resulted in mixed messages and competing priorities being disseminated to providers.

The current process for making changes to improve the ALB landscape is currently unsatisfactory in a system where the NHS is ever evolving. This power is designed to provide greater resilience to future system stresses, and to support and foster the flexibility that ALBs have shown in dealing with the pandemic. It will allow the system to adapt and shift to changes in priorities and focus over time, rather than having to introduce complex and bureaucratic workarounds.

The following ALBs will be explicitly out of scope of the power given their particular technical and regulatory functions, and their need to maintain independence of decision making:

- Care Quality Commission (CQC)
- National Institute for Health and Care Excellence (NICE)
- The Health Services Safety Investigations Body (HSSIB)

Executive Agencies, such as the Medicines and Healthcare products Regulatory Agency (MHRA), are legally part of DHSC, meaning that the Secretary of State can already make arrangements for their functions to be carried out by other bodies.

Otherwise, a wide range of Special Health Authorities and Non-Departmental Public Bodies will be within the scope of the power.

Costs

There are no direct costs from the introduction of this provision. However, there may be indirect costs which will depend upon if and how the power is used. For example, if the power is used to transfer functions to or from an ALB, this may incur administrative costs such as those associated with staff transfers, changes to websites and publicity of these changes to stakeholders. Specific costs cannot yet be quantified as it would depend on the extent of functions being transferred and the organisations involved. This will be considered as part of any transfer of functions and the relevant enabling legislation.

Benefits

The ability to transfer functions across ALBs will make it easier for the system to respond to differing challenges such as pandemics or winter pressures more swiftly in future.

This provision will provide a flexible solution to the question of how to adapt swiftly the ALB landscape to meet emerging challenges facing the NHS. At a time when the NHS is constantly evolving, the current process for amending the functions of ALBs, which requires the passage of primary legislation, is unsatisfactory. By giving the Secretary of State the power to transfer functions through secondary legislation, the provision would enable the system and the Government to continue to respond to new pressures at speed and continue to deliver on the NHS's usual objectives. The Health and Social Care Act 2012 was based on the idea that there was a range of autonomous bodies with fixed roles in the system holding each other to account within a rules-based system. As the system moves away from

that to a more collaborative, flexible approach to delivering the best health and care outcomes for people, the ALB landscape also needs to be flexible and adaptive.

Risks

There is a risk that the future use of this power will result in organisational uncertainty for the NHS. While the use of the power by the Secretary of State should be proportionate and executed with the intention that the change will be of overall benefit to the NHS, there is still a risk that this could create an operational distraction.

Mitigations

Several mitigations have been incorporated into the policy against these risks. Firstly, the HSSIB, CQC and NICE are excluded from the scope of the power as these are regulatory organisations with roles that depend on remaining independent from other parts of the NHS. As a result, it would be inappropriate for these organisations to have their functions altered without appropriate democratic oversight. Executive Agencies, such as the MHRA, are legally part of DHSC, meaning that the Secretary of State can already make arrangements for their functions to be carried out by other bodies.

Secondly the choice of an affirmative resolution procedure ensures that both Houses of Parliament will have the chance to scrutinise the use of the power; members of these Houses can receive representations from organisations usually consulted on changes to ALBs.

Finally, this power will enable the movement of existing functions to and from ALBs but will not be used to create new functions.

Before any changes are implemented to the ALB landscape using the power, there will need to be a minimum six-to-eight month process involving consultation with relevant ALBs, and devolved administrations where appropriate; due diligence of the terms and conditions of affected staff; pension implications; geographical considerations; decisions around ALB Boards; and consideration of any shared or back-office functions. These processes should prevent undue organisational upheaval.

15. General power to direct NHS England

Policy summary

This provision will give the Secretary of State for Health and Social Care a power to direct the newly formed NHS England. This will allow the Secretary of State to direct NHS England on its functions, with specific exemptions for functions involving individual clinical decisions, decisions related to the NICE process and appointments. The intention is that this power will strengthen the Secretary of State's existing powers of intervention over NHS England, as a proportionate measure in response to the concentration of national functions and powers within NHS England as a single organisation. The provision will be accompanied by the repeal of existing duties to promote autonomy on NHS England and CCGs.

This power is needed in response to the evolution of the system in recent years and the changes that the Act bring in to take that evolution further. It is important to emphasise that the power is not a general power over the NHS but, rather, a power to direct NHS England (in its new, merged form) with respect to its functions. The power will sit alongside other powers such as the power to set a mandate for NHS England and the power to appoint the chair of that body. Taken together, these powers (including the new power over NHS England) would give the Secretary of State the ability to address both strategic and more

immediate issues in a proportionate, agile and timely manner. This will help to reinforce the connection between NHS decision making and democratic scrutiny and oversight.

Costs

Direct costs arising from this provision are expected to relate to any new reporting or transparency arrangement; these will depend on the guidance, to be set out, around how the new power can be used but are expected to be small. Indirect costs, arising from specific uses of the new power, cannot yet be quantified.

Benefits

This proposal could have the benefit of reduced bureaucracy as both the Secretary of State and NHS England will be able to more easily express their priorities. Clarity of expectations is meant to lead to better outcomes, along with requiring fewer incentives and less performance management to deliver on objectives.

Risks and mitigations

There are simultaneous risks that the Secretary of State will either use the Power of Direction more often than is helpful (and more than is envisaged) providing the system with further administrative burdens and legal obligations; or that it will not be an effective tool in driving change. There is also a risk that the intended benefits of reduced bureaucracy do not materialise, with DHSC and NHS England moving to a more formal, less cooperative way of working.

Government is expected to set out transparency arrangements for use of the power.

Any direction made by the Secretary of State must be made in writing, published and be made in the public interest. Ministers are also limited in their use of the new power by the usual public law principles. The public scrutiny of the use of this power should counter any possible reputational and practical risks associated with over, or under, utilising it.

16a. NHS England Mandate: general (and Better Care Fund)

Policy summary

The Act amends mandate setting provisions to enable the mandate to be used more effectively and flexibly as a strategic objective setting tool.

Pre-Act, the Secretary of State was required to publish a mandate to NHS England before the start of each financial year under Section 13A of the 2006 NHS Act. The mandate had to specify the objectives that NHS England should seek to achieve along with any requirements that it should comply with in order to do so. It also had to confirm the capital and revenue resource limits that NHS England should work within. Changes included in the Act:

- Amend Section 13A to remove the former duty to publish and lay a mandate annually before the start of the financial year, instead requiring the Secretary of State to have a mandate in place.
- Remove the duty to include in the mandate the annual limits on capital and revenue resource use – these are replaced with a duty to do this in financial directions which were previously optional but will in future be mandatory and will be laid in Parliament as well as published.
- Remove the power to direct NHS England to use a specified amount of funding to further the integration of health and social care (currently achieved through the Better Care Fund), and meet conditions set for the funding by including this as a

requirement in the mandate. The Act replaces this power with a separate power of direction that has equivalent effect.

Costs

As now, decisions on the annual revenue and capital resource limits for NHS England will continue to reflect wider financial decisions on health and care, including through Spending Reviews, the Budget and other negotiations. These decisions will simply be given statutory effect through annual financial directions rather than the mandate document but will be taken into account (as they are now) in developing mandates to ensure that expectations in mandates remain affordable. No additional administrative costs are expected to arise from this measure.

Benefits

The annual deadline for laying and publishing a new mandate made it increasingly hard for the mandate to reflect the outcome of Government's wider strategic decisions on health and care that are not aligned to the financial cycle – including in light of Spending Reviews and Budgets that occur late in the financial year. These changes will better support the Secretary of State in ensuring that the strategic direction that he sets for NHS England through the mandate is fully aligned to broader Government priorities for health and care and is also responsive to changing need.

Provision for a mandate to be continuously in place, but not explicitly tied to the annual cycle, offers greater flexibility on when, and how often a mandate must be revised. This will enable the Secretary of State, where appropriate, to set longer term objectives and underpinning delivery expectations. Covid-19 demonstrated that there will also be times when the NHS needs to transform at much faster pace, and so it will also be possible for the Secretary of State to revise a mandate after a shorter period to respond to rapidly changing need as well as to reflect new strategic commitments, emerging evidence or other unforeseen external events that impact on the NHS.

Risks and mitigations

The main risk is that delinking the mandate from financial instruments (revenue and capital limits, the Better Care Fund) and the financial annual cycle, leads to a disconnect between Government decision making on the priorities that should be set for the NHS, and the affordability of those priorities. The mandate will by its nature always need to be reasonable and deliverable with the capital and revenue funding that the Government has allocated for NHS England. However, this risk has been further mitigated through the proposed strengthening of statutory annual financial directions to NHS England so that these will be mandatory and will need to be laid in Parliament to ensure there is full transparency about the financial resources that NHS England has available to it in each financial year.

There is also a risk that frequent revisions to the mandate could hamper NHS planning and contracting decisions that align with the annual finance cycle. There continues to be a duty on the Secretary of State to consult NHS England, Healthwatch England and any other persons he considers appropriate before revising the mandate. The Act also makes clear that NHS England will not be required to amend its own business plan if the mandate is revised in under a year from the previous revision..

16b. NHS England mandate: cancer outcome targets

Policy Summary

The Act creates an additional duty for the Secretary of State to include in the mandate for NHS England one or more objectives relating to cancer, framed in terms of outcomes (such

as one-year or five-year survival rates, patient experience and quality of life). It also gives these objectives priority over any other objectives in the mandate relating specifically to cancer.

The NHS Long Term Plan (LTP) set a new ambition that, by 2028, the proportion of cancers diagnosed at stages 1 and 2 will rise from around half now to three-quarters of cancer patients with a stageable diagnosis – this is a deliberately challenging ambition. Achieving this will mean that, from 2028, 55,000 more people each year will survive their cancer for at least five years after diagnosis. Priorities include early diagnosis, faster diagnosis, investing in new equipment and workforce, speeding up innovation to business-as-usual, personalised care and follow-up pathways.

Costs

This amendment does not directly impact planned spending on cancer treatment, and no additional direct financial costs are expected to arise as a result of it as NHS LTP funding covers the existing cancer commitments. However, as noted under Risks, depending on how this is applied, it could lead to opportunity costs, and potential allocative inefficiency, if high-benefit non-outcomes-based cancer interventions are displaced.

Benefits

The change may complement current ambitious cancer stage and survival targets outlined in the NHS LTP (see above). Realising these potential benefits will depend on how the amendment and subsequent mandate affect prioritisation of clinical and non-clinical activity relating to cancer. The benefits of the amendment are therefore unclear at this stage.

Risks and mitigations

The amendment may cause unintended consequences due to the prioritisation of objectives relating to cancer outcomes for patients over other cancer related objectives. Prioritising outcomes may have a negative impact on other LTP commitments if other objectives for cancer outlined in the mandate are deemed to be ‘process-driven’ as opposed to outcomes-focused.

As such, the change could risk being perceived as deprioritising ‘process targets’, which in practice may mean waiting times targets, some of which are targets set out in legislation and which are incredibly important for patients and also to incentivise services to streamline pathways.

Furthermore, introducing an increased priority on cancer outcomes may create incentives for the health system which could lead to clinicians carrying out some cancer treatments that may indirectly result in the delay or cancellation of other activities that would ultimately have resulted in a greater health benefit. It may therefore reduce the overall (cost-) effectiveness of the health service.

As outlined in section 16a, the mandate is intended to be flexible to ensure that it reflects up to date Government strategic priorities; any legislation requiring certain objectives be prioritised impacts on this flexibility and efforts to improve outcomes under uncertain future circumstances.

Prioritising cancer outcomes as a result of this amendment may mean using a historic measure to assess performance, rather than more timely ones. This may cause challenges in assessing current performance. For example, using a longer term outcome measure, such as the five-year survival rate measure outlined in the NHS LTP, would mean a potential lag of seven-years before the impact from a mandate objective framed in terms of outcomes is

visible in the data. If instead performance is based on measures with a shorter lag, such as waiting times, this may reduce challenges in trying to assess current performance. A potential risk of focussing solely on outcomes is, therefore, a delayed ability to respond to changes in performance.

17. Reconfiguration of services: intervention powers

Policy summary

The power to intervene in health service reconfigurations will enable the Secretary of State to call-in service change proposals at any point in a reconfiguration process. It will also enable the Secretary of State to act as a decision-maker in relation to service reconfigurations they have called in. When the section is commenced, the Local Authority (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013 (the 2013 Regulations) will be amended in parallel to remove the power for Local Authorities to refer proposals to the Secretary of State – in practice this route will be replaced with the ‘call in’ power.

In addition, the power will create a duty on NHS commissioning bodies to notify the Secretary of State of a ‘notifiable’ proposal to reconfigure NHS services, with the description of “notifiable” provided for in regulations. It is the Department’s intention to use those regulation to align the notification duty with the existing duty for those responsible for a reconfiguration to consult a Local Authority on it.

Hospital and community health services in the NHS are often subject to service reconfigurations – changes in the provision of care – usually as part of a reorganisation of services across a larger health geography. Reconfigurations, most frequently associated with the location or the type of treatment provided, can occur for a variety of reasons, for example in response to financial or workforce pressures, to provide more clinically effective outcomes, improve patient access to healthcare or react to new medical and technological developments⁵². The scale of possible change is broad, from the small-scale closure of a GP surgery to a more significant replacement of a number of stroke units with a centralised hyper acute stroke unit.

Reconfigurations are locally led by the NHS, and where a service change is deemed to be a substantial development of the health service or a substantial variation in the provision, the local NHS is required to consult the relevant local authority’s oversight and scrutiny committee (OSC), or joint OSC where appropriate, for example where a service change relates to a wider region. Where the OSC feels consultation has not been timely or adequate, or the change may not be in the local interest they have a right of referral under the 2013 Regulations to refer the matter to the Secretary of State, who will seek independent advice from the Independent Reconfiguration Panel.

NHS England’s *Planning, assuring and delivering service change for patients* guidance⁵³ sets out best practice for ‘substantial service change’. This guidance sets out the need for a clear clinical evidence case underpinning reconfigurations, and recommends that for complex service change commissioners should consider Clinical Senate advice. Clinical

⁵² Reconfiguration of NHS services (England), House of Commons briefing paper, 2017. [Online]. Available from: <https://commonslibrary.parliament.uk/research-briefings/cbp-8105/>

⁵³ NHS England, ‘Planning, assuring and delivering service change for patients’, 2018. [Online]. Available from: <https://www.england.nhs.uk/publication/planning-assuring-and-delivering-service-change-for-patients/>

Senates were instituted in April 2014 and are the primary source of external clinical advice and support for local teams leading a reconfiguration. Clinical Senates conducted 114 clinical reviews (ranging from 14 to 26 per year) in the 2014-2019 period⁵⁴, giving us a partial perspective on the number of complex reconfigurations in England. Between 2007 and 2012, the National Clinical Advisory Team – which for this period provided the clinical support now expected of Clinical Senates – reviewed 124 reconfigurations (which ranged from 6 to 28 per year)⁵⁵.

The current system for reconfigurations works well in the main and the intention is to leave it in place for the majority of service changes. There are, however, some reconfigurations that give rise to significant cause for public concern and can lead Ministers to assess that there is a strong rationale to take a particular course of action. Other than the OSC referrals under the 2013 regulations, there is no formal mechanism that would allow the Secretary of State for Health and Social Care to intervene in a service reconfiguration or take a decision on a reconfiguration matter. This limited ability to intervene is particularly important now, given the ongoing government programme to deliver 40 hospitals as part of the Health Infrastructure Plan and the development of new ways of delivering care in response to demographic change and as part of the recovery from the pandemic.

Costs

Costs are ultimately dependent on how the Secretary of State chooses to use the new intervention power over reconfigurations. The number of specific reconfigurations in which the Secretary of State is expected to intervene as a decision-maker is small. The Secretary of State will only be notified of 'notifiable' reconfigurations, which will be defined, through regulations, as those reconfigurations which represent a substantial development of the health service in an area or a substantial variation in the provision of a service, and we intend for this to set an indicative threshold for services in which the Secretary of State should intervene – as a matter of policy we expect a similar threshold to be applied to the call in power, although legally the Secretary of State can intervene in reconfigurations of any size.

If the Secretary of State does intervene this could add up to six months to the reconfiguration timeline (it is limited to 6 months owing to the time limit for a decision put on the Secretary of State). As a result, there could be increased costs to the NHS and local healthcare systems such as: administrative costs to respond to the Secretary of State queries, cost of contract extensions with builders, and delayed realisation of efficiency savings.

In addition, the ability to call-in any reconfiguration could lead to new departmental administrative costs. These include:

- Costs associated with providing administrative support for the new system and, in particular, to source the clinical advice ministers might need to make effective and defensible decisions; this would complement the expert advice currently available through the [Independent Reconfiguration Panel](#), or may require new resource to the Independent Reconfiguration Panel itself.
- Costs associated with creating effective data flows and information links on service changes. This would be necessary to ensure the Secretary of State has appropriate information across reconfigurations to be able to call them in. This could be a particularly significant cost if cases monitored for call-in extended much beyond the remit of complex reconfigurations Clinical Senates have visibility over (15-25 per

⁵⁴ Repository of all the work conducted by Senates across England, available at <https://secsenate.nhs.uk/wp-content/uploads/2020/07/National-Clinical-Senate-Topic-Log-March-20-MASTER.xlsx>

⁵⁵ Imison et al, 'Insights from the clinical assurance of service reconfiguration in the NHS: the drivers of reconfiguration and the evidence that underpins it – a mixed-methods study', 2015.

year), and if duplication with data flows to other bodies (ICBs, NHS England, Local Authorities) could not be avoided. This could, for example, involve a new IT system to manage the influx of notifications to Secretary of State.

Benefits

Benefits are ultimately dependent on how the Secretary of State chooses to use the new reconfiguration of services intervention power. The new power would enable the Secretary of State to intervene in challenging reconfigurations earlier, whenever he deems most appropriate, rather than waiting for a Local Authority referral. The main potential benefit would be a reduced number of proposed reconfigurations reaching a deadlock locally. This could also, in some cases, mean that a successful conclusion was reached more rapidly and thus time and energy that would otherwise have been lost would be available for other purposes within the system.

Risks and mitigations

The role of service change consultations – involving patients and the public – will be unchanged, and not be subject to ministerial decisions directly. Likewise the responsibilities for local authorities to scrutinise change will remain. However, in practice, broader and more active lobbying groups may press the Secretary of State to intervene.

To ensure local voices are heard, and to recognise the important role local authorities continue to have in scrutinising reconfigurations, the Secretary of State must give local authorities, commissioners, and anyone else they consider appropriate the opportunity to make representations to them once they have called in a reconfiguration.

To ensure equitable reviews, the department will need new administrative processes to provide adequate support to ministers (including clinical expertise); and new data flows allowing adequate scrutiny of complex reconfiguration cases prior to call-in, as described in the Costs section.

The health outcomes of people who use services may be affected by intervention from the Secretary of State. An illustrative example is that an intervention may lead to patients achieving different health outcomes versus a scenario where there was no intervention (irrespective of timings). It is plausible that an intervention leads to better health outcomes, but there is a similar risk that health outcomes would have been better were the intervention not to have occurred. However there are several mechanisms in place to mitigate these risks. The Secretary of State has a series of legal duties that apply in the exercise of all of his functions, which will apply when he calls in and decides upon a reconfiguration. In particular, he must exercise his functions with a view to securing continuous improvement in the quality of services, promotion of a comprehensive health service and reducing inequalities. The Secretary of State must also publish his reasons for taking a decision, ensuring the decisions he has taken are transparent. As a matter of good practice, the Secretary of State will continue to be advised on all of his decisions by the Independent Reconfiguration Panel, an expert panel providing recommendations on any proposal the Secretary of State calls in.

18. Public Health power of direction

Policy summary

This provision confers a power on the Secretary of State to be able to require NHS England and ICSs to exercise any of their public health functions. At present, the Secretary of State

can arrange for NHS England, a CCG, local authority or combined authority to exercise any of his public health functions, but this requires an agreement by both parties. Services in scope will include national immunisation programmes, national screening programmes, and public health services for adults and children in secure and detained settings in England.

This provision will provide an additional mechanism to ensure effective preparations are made and services are delivered by the NHS for medium and long-term challenges, particularly annual winter pressures and the recovery and renewal needed following Covid-19.

Costs

It is expected that the delegation of public health functions will continue working on the basis of agreement in most circumstances. In the rare occasions requiring direction, this would likely change the *timeline* of agreement rather than the *outcome*; additional costs, if any, are therefore expected to be very limited.

NHS England is financed for exercising the Secretary of State public health functions as part of its overall mandate funding envelope; this provision will not of itself change the funding envelope.

Benefits

The delegation of public health functions is expected to continue working on the basis of agreement in most circumstances. In the rare occasions requiring direction, the power provides a decisive way to resolve a real or apparent impediment which could otherwise frustrate the ability of the Secretary of State to discharge functions and duties placed on him in statute in the most effective way, or where directions would be desirable for purposes of timeliness and clarity. The provision of effective preventive services can also help the NHS to reduce costs in the round – for example, wide scale provision of flu vaccinations helps to reduce demand on the NHS during winter when it is also likely to be contending with Covid-19 and pressures from reduced elective capacity.

Risks and mitigations

There is a theoretical risk that the power could be used to require additional functions to such a degree that, alongside the other legal responsibilities placed on NHS England, the organisation would not have the capacity to carry out these functions and legal obligations in the manner requested. While the Power of Direction could compel NHS England to conduct the functions in a certain way, it is highly unlikely that this would happen without appropriate prior discussions and awareness of burdens on capacity and resources.

19. Abolition of Local Education Training Boards

Policy summary

This provision removes Local Education Training Boards (LETBs) from statute, following which, Health Education England (HEE) will have flexibility to set its regional operating model. HEE is the Arm's Length Body (ALB) responsible for the planning and delivery of education and training for the NHS and public health workforce in England. HEE is supported in its work by a network of LETBs. These are statutory sub-committees of HEE. Their function is to exercise HEE's functions at local level i.e. responsible for the training and education of NHS staff (both clinical and non-clinical) at a local level. However, this can be

achieved through HEE regional staff accountable to the HEE Board working with local NHS Bodies on an individual basis or appropriately overseen at a place-based level.

LETBs have become outdated and it is important that HEE have the flexibility in establishing its regional operating model to allow greater joint working with the (non-statutory) Regional People Boards and ICS. The functions that would have been carried out by LETBs will continue to be undertaken by HEE staff reporting to the HEE Board.

LETBs were established to; develop and deliver local education and training plans; and to allocate HEE resources to deliver the right workforce for the constituent population. This work largely consisted of the commissioning of undergraduate clinical places and overseeing the delivery of commensurate contracts with Higher Education Institutes ('HEIs') to deliver the places available. Reforms to healthcare education funding started to take effect from 1 August 2017, with most non-medical healthcare students moving from a bursary-based funding model to loans-based. The cap on student places operated by HEE and its LETBs was removed and has enabled HEIs to expand places and allowed a market-based system to thrive. Therefore, the role of the LETB in overseeing the delivery of the commissioning of pre-registration healthcare courses has significantly diminished as a result. The LETBs also oversee the local allocation of workforce development funding.

If LETBs were not abolished, the statutory HEE functions within their remit would be considered at regional and/or ICS level alongside other workforce matters. HEE Staff and/or the LETB Chair would represent HEE in these discussions.

This would create duplication of effort and consequent waste of public money as the LETBs would need to meet separately from the Regional People Board to formally make the decisions on the HEE functions.

When operationalising this provision, LETBs would continue until they are abolished under section 90 of the Health and Care Act. HEE would wind down the formal LETB structures with the work reverting to HEE.

Costs

It is not anticipated that there will be any direct costs associated with abolishing LETBs. LETBs are not employers, and the staff supporting LETBs are employees of HEE and will continue to perform HEE's regional duties. The work of LETBs will continue to be undertaken by HEE directly. It is not expected that there will be significant business disruption stemming from this change.

Benefits

There are small savings for HEE. LETB chairs are appointed on an annual basis by the HEE Chair and are paid by HEE the same rate as a HEE Non-Executive Director (£7,883 pa). There were seven LETBs matching NHS England's regional footprint. Once LETBs are abolished, the LETB Chairs will no longer be required. **The saving are therefore £55,181 per annum**, notwithstanding any overheads which are expected to be small.

The main benefit of abolishing LETBs is a reduction in bureaucracy which will make operational decision - making on workforce activities more holistic at regional level. The proposal was put forward by HEE to allow them flexibility in their regional operating model.

Risks and mitigations

It might be argued that this provision takes away clarity of accountability from statute as statute will no longer set out responsibility for education and training at local level. However, HEE will retain responsibility with the former LETB functions continuing to report to the HEE Board. In addition, under Section 41 of the Health and Care Act, a duty is placed on the Secretary of State to publish a report at least every 5 years describing the workforce planning and supply system which will provide that greater transparency.

20. Workforce Accountability

Policy summary

This provision places a duty on the Secretary of State to publish, at least once every 5 years, a report setting out how responsibility for the workforce planning functions of the NHS are being taken forward. This report will describe the workforce planning and supply system, including, the roles of DHSC, ALBs, NHS bodies and others, and how they work together in practice. The report would assist stakeholders as it would provide them with clarity and transparency as to how the workforce system operates. The bodies with workforce planning responsibilities set out in the report (HEE, NHS England, ICBs) would be held to account through their normal accountability mechanisms of objective setting and review. Additionally, the Secretary of State could be challenged if he failed to publish the report.

NHS England's 2019 engagement process around their recommendations for legislative reform raised some issues around the respective responsibilities of national organisations in relation to workforce functions. As part of a wider petition organised by the Royal College of Nursing, the following points were made: "Expanding powers for the Secretary of State for Health and Social Care provides a clear opportunity to articulate the new duties for workforce that we have called to be included in this legislation". A number of other respondents to NHS England's consultation felt there should be greater clarity on which organisations are specifically responsible for ensuring adequate levels of funding for NHS staffing, including UNISON, and also the Royal College of Physicians. In responding to the Royal College of Nursing (RCN), UNISON, and other royal colleges, NHS England recommended that the Government should now revisit with partners whether national responsibilities and duties in relation to workforce planning were sufficiently clear. The Department of Health and Social Care agreed that, under the current system, there is scope to improve transparency in the operation of the workforce planning and supply. In response to this, the Act makes the publication of the workforce report a statutory requirement. The report will set out the roles of the different organisations involved in workforce planning at national, regional and local level. However, the Act does not set out ALB responsibilities in primary legislation in more granular fashion than currently in existing legislation. Our view is that workforce planning is covered within the current existing legislation, and to set out specific workforce planning functions for individual ALBs would create an inflexible approach and go against the wider principle of not being too prescriptive in the Act, recognising that system architecture evolves. Furthermore, HEE and NHS England are accountable to the Secretary of State for carrying out their functions through the process of objective setting and review, which are legal functions of the Secretary of State. Committing to publish this report supports the Act's key principle of ensuring public confidence and accountability by ensuring that the right framework is in place for oversight of our health system, that national bodies are streamlined with clear roles and responsibilities, and that the public and Parliament can hold decision makers to account.

The DHSC has also considered and rejected:

- An additional duty or an amendment to Section 1F(1) of the NHS Act 2006 for the Secretary of State to be responsible workforce planning. The effect of such an amendment would have been to allow Secretary of State to delegate workforce planning to ALBs either in total or to specify in primary legislation which ALB would be responsible for which aspects of workforce planning.
- The introduction of safe staffing legislation akin to the Nurse Staffing Levels (Wales) Act 2016 and Health and Care (Staffing) (Scotland) Act 2019.

DHSC is also taking non-legislative action on workforce planning separate to the Health and Care Act. In July 2021, DHSC commissioned Health Education England to work with partners and to review and renew the long-term strategic framework for the health and regulated social care workforce, to help ensure we have the right skills, values and behaviours to deliver world leading services and continued high standards of care. This work is now nearing completion. Building on this work, DHSC has also recently commissioned NHS England to develop a long term workforce strategy, and key conclusions from this work will be available in due course.

Costs

There are potential costs associated with resourcing civil servants to draft the reports, although these are expected to be small and have not been quantified.

Benefits

The benefit of this policy is greater transparency and accountability for workforce planning and supply. These benefits would be accrued by external stakeholders (e.g. the RCN) who would be able to use the information provided to hold the system and the Secretary of State to account for ensuring an effective system of workforce planning was in place. Stakeholders would be able to identify where workforce planning was not happening as envisaged by the report and raise it with the Secretary of State or the bodies identified. The benefits of greater transparency and accountability will more generally be felt by providers, patients and the taxpayer.

Risks and mitigations

A potential risk is that the provision does not create greater transparency over the workforce planning system as the report is a description of the current state of play, rather than a prescriptive set of actions. However, it is hoped that this will be mitigated by the report providing clarity on the current situation and the areas in which improvements can be made.

21. Designating Integrated Care Boards as Operators of Essential Services under NIS Regulation

Policy summary

Integrated Care Boards (ICBs) will be established as statutory bodies via the Health and Care Act. Assurance is needed to ensure ICBs comply with the required standards in order to reduce cyber risk.

This amendment designates ICBs as Operators of Essential Services (OES) under the Network & Information Systems Regulations 2018 (the NIS Regulations). This would bring ICBs into an established regulatory framework for cyber security alongside NHS Trusts and

large independent healthcare providers, and mean that ICBs must fulfil the security duties under the NIS Regulations.

The NIS Regulations came into force in May 2018. They provide for legal measures aimed at boosting the overall level of security (both cyber and physical resilience) of network and information systems for the provision of essential services and digital services in those sectors which are vital for our economy and society (such as healthcare, transport and the supply of electricity and water).

The Regulations require organisations identified as 'operators of essential services' (OES) to fulfil security duties to:

- take appropriate and proportionate measures to manage risks posed to the security of the network and information systems on which their essential services rely;
- take appropriate and proportionate measures to prevent and minimise the impact of incidents affecting the security of the network and information systems used for the provision of essential services; and
- report incidents that have a significant impact on continuity of essential services.

The NIS Regulations are overseen by 'competent authorities' which fulfil a similar role to a regulator, with the duty to issue guidance and the power to inspect organisations and take enforcement action (including imposing penalties of up to £17 million) where necessary. The Secretary of State for Health is the Competent Authority for the Health Sector.

In England, healthcare services are an essential service for the purposes of the NIS Regulations. Currently, NHS Trusts and Foundation Trusts, along with 28 large independent healthcare providers are deemed or designated as OES or 'operators of essential (healthcare) services' for the healthcare settings sector in England for the purposes of the NIS Regulations.

DHSC will publish updated guidance on the NIS Regulations that will inform OES (including ICBs) of their responsibilities under the NIS Regulations, and the powers that the Secretary of State through DHSC has as Competent Authority. ICBs would be required to complete an annual Data and Security Protection Toolkit (DSPT) assessment which will be used to assess their cyber security posture. Once ICBs are designated as OES, they will be required to report any incident that affects their network and information systems (providing the incident meets certain impact thresholds, which are also published in guidance via the DSPT).

DHSC expect local ICBs to be taking local level decisions on IT investment (including around cyber security) across their regions, as well as owning systems and the associated cyber risk for systems that are critical to the provision of healthcare. This includes taking some responsibility for the provision of GP IT services from Commissioning Support Units (CSUs). They will also hold the Shared Care Record, and the associated cyber risk, the loss or corruption of data from which could have clear implications for delivery of care, as well as wider public trust in the digitisation and data sharing agenda. Accordingly ICBs should be subject to a robust and focussed regulatory framework for the management of cyber risk. The NIS Regulations provide such a framework and are designed to raise security standards.

There are two principle drivers behind the need to close this regulatory gap:

1. Some of the critical systems that ICBs will own, along with the associated cyber risk, are already in development by the Integrated Care Systems that have been

established, and will expand rapidly in both scale and criticality over the next year.

Shared Care Records (ShCR) - which aim to create care records that can be shared between health and care providers - are one such system. Almost all of the 42 ICS already have a basic ShCR in place with the remainder to complete within the next few months. Across the country hundreds of organisations are now connecting into shared care records. Those connections will continue to grow over the coming months and years as will the functionality and scope of the existing shared care records.

NHSX will shortly be publishing ShCR standards to ensure the developing systems are secure by design, but this must be combined with an effective compliance mechanism, and the appropriate regulatory levers to allow Government to step in to gain assurance that critical systems are being adequately protected. While standards will be largely focused on the suppliers of ShCR solutions to ensure the security of design and operation, we need powers to gain assurance of the ICBs as data and risk owners. Without amendments to the NIS Regulations via primary legislation to ensure that ICBs are covered by NIS, DHSC will have limited enforcement and compliance measures governing the cyber security of these new patient data sharing arrangements.

2. Regulatory oversight drives compliance with cyber security standards and ensures that vulnerabilities are remediated quicker. Since 2019, DHSC has used its power to issue NIS Information Notices to NHS Trusts (who are deemed OES under the NIS regulations) that require them to address critical cyber vulnerabilities on their networks. Such cyber vulnerabilities are identified in network and information systems regularly and affect all sectors - they are generally fixed by applying patches. Where particularly important vulnerabilities are identified, High Severity Alerts are issued to Trusts, requiring that they acknowledge the alert within 48 hours and remediate the problem within 14 days. The use of NIS Information Notices, combined with communicating the further NIS enforcement action that we could take in the event of non-compliance, has driven compliance with High Severity Alerts and led to the swifter remediation of vulnerabilities. The vast majority of Trusts now acknowledge the alert within the 48 hour deadline (compared to around half in 2019), and either mitigate the vulnerability, or provide an adequate mitigation plan by the 14 day deadline. Without NIS powers over ICBs, DHSC will have limited power to gain assurance that critical vulnerabilities are being adequately addressed, possibly leading to vulnerabilities sitting on their networks for several months, which could lead to a disruption in the provision of care, or a security breach in relation to the shared care record, both of which could realistically lead to patient harm. With 7 High Severity Alerts in 2020, and 8 so far in 2021, this issue alone poses a significant risk.

For context, it is worth noting that one major factor that caused Trusts to be affected by the WannaCry cyber attack in 2017 was failure to implement vulnerability updates recommended by NHS Digital. Legacy systems across the NHS were also a key factor (i.e. systems no longer supported by the manufacturer with security patches). DHSC are currently using our NIS powers as a key part of a programme to reduce the number of unsupported Windows devices in NHS Organisations. Given the critical role that ICBs will play in the healthcare system, it is important that this same regulatory drive for improvement should apply to them also.

In summary, without designating ICBs as OES, there would be a significant gap in the regulatory framework. Although individual organisations are responsible for their own cyber security (and ICBs will be responsible for the cyber security of any IT provision that they provide), as system stewards we have a duty to assure that organisations are taking their responsibility seriously, as well as managing the cyber risks to the wider health care system should there be a large scale cyber attack or an incident with wider ranging impacts.

In putting forward this policy we have consulted with the Department for Digital, Culture, Media and Sport (DCMS) and ensured that this policy expansion is in line with future legislative proposals.

Costs

This amendment will come at no cost to private businesses. The only possible cost impact will be on ICBs, which are the only organisations affected by this amendment. However, NIS compliance in the health and social care sector has been built into existing compliance mechanisms, in an attempt to reduce the burden on OES. The main compliance tool is an annual self-assessment, the Data Security and Protection Toolkit (DSPT). All bodies that process the confidential patient data of citizens who access health services are already required to complete this self-assessment, so this requirement would be placed on ICBs regardless of whether they are designated as OES under the NIS Regulations.

The NIS Regulations stipulate that OES must take appropriate and proportionate measures to fulfil their security duties of the Regulations (see policy summary above). It is our view that the kind of 'appropriate and proportionate measures' that will be required of ICBs are reasonable expectations for any organisation that provides an essential public service (including adequate backups, timely patching of vulnerabilities, appropriate life cycle management of software etc.) However, the NIS Regulations give us the ability to take action where these reasonable expectations are not being met.

DCMS has overall responsibility for the NIS Regulations and has published a post-implementation review⁵⁶ in May 2020 with the following cost estimates. These figures are cross-sector estimates for all OES (health, transport, water, energy etc.). There will be some variance based on size and scale of the OES in question, amount of operational technology for some OES in addition to standard IT etc. but we can expect ICBs to fit somewhere in these estimates. :

- The one off cost of familiarisation per organisation is estimated to be £655.36 per organisation (comprising the salary costs of legal and senior management time).
- The cost of incident reporting is estimated to be £54 per incident. There are already requirements for organisations to report incidents to NHS Digital, so this cost is not new.
- DCMS estimate additional compliance costs of reporting requirements to Competent Authorities - such as completing the Cyber Assessment Framework or another type of assessment - as £80 for a small organisation, £275 for a medium sized organisation, and £549 for a large organisation. ICBs will already be required to complete the DSPT self assessment, so this cost is not new.
- The post-implementation review also attempted to estimate the costs of additional security spending that would be incurred by organisations due to the introduction of the Regulations. Spending was divided into three categories: internal staff costs;

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960574/CCS207_CCS0320329850-001_Network_and_Information_Systems_Regulations_Post-Implementation_Review_Web_V2.pdf

physical security; and external costs, with additional spending envisaged on measures such as increasing staffing, investing in IT software, additional risk assessments and audits, staff training and testing and monitoring systems.

- It is worth noting that these are cross-sector estimates - some OES are FTSE 100 companies. Any additional security spending by individual organisations will vary by the existing measures and technical controls they have in place, and the extent to which they judge additional spending to be appropriate to comply with the requirements of the NIS Regulations. As ICBs will be classed as OES under the NIS Regulations from the point of their statutory establishment or soon thereafter, they can take this into account when procuring and building network and information systems, and should not need to retrospectively consider and procure security measures. The cost of ensuring that network and information systems are secure is to a large extent a normal cost of business.
- With the above context in mind, the table below shows estimates for how much an OES could spend on putting additional security measures in place as a result of being designated as an OES under the NIS Regulations. These are taken from the aforementioned DCMS post-implementation review and the DCMS impact assessment that fed into it. These figures are based on survey responses to the question of spend in the past 12 months, or estimated spend in the next 12 months. The question divided spending into three categories: internal staff costs; physical security; and external costs, with physical security assumed to be a one-off cost and internal and external costs assumed to be annual. If we are to assume that as commissioning bodies, ICBs will have balance sheets that put them into the category of large OES, then an estimate of cost to the system could be calculated by multiplying the low and high estimated costs by the number of ICBs, giving a figure of £4.2 - £8.4 million. However, for the reasons set out above, this figure is perhaps not reflective of the unique position of ICBs among other OES, and we would expect many of the costs of security spending to comply with NIS to be absorbed into the normal spending on cyber security that would be expected from an organisation looking to protect its systems and comply with existing regulations (such as GDPR, DSPT etc.)

Estimates for how much an OES could spend on putting additional security measures in place as a result of being designated as an OES under the NIS Regulations (12 month period)

	Small OES (not more than 50 employees, turnover <£10.2m, balance sheet total <£5.1m)	Medium OES (not more than 250 employees, turnover <£36m, balance sheet total <£18m)	Large OES (more than 250 employees, turnover >£36m net, balance sheet total >£18m)
High estimated additional costs per business	£1,400	£75,000	£200,000
Low estimated additional costs per business	£500	£50,000	£100,000

Benefits

Designating ICBs as OES means that ICBs are subject to the NIS Regulations. This puts in place the requirements outlined above which will improve the security of the network and information systems which ICBs control. As the Competent Authority, this also allows DHSC cyber-specific powers of inspection where there are serious suspected failings, a legal

mechanism to require information, for example, about the cyber security of their networks, or to take enforcement action, for example, to require improvements where weaknesses are discovered that could result in a severe interruption to essential services.

Risks and mitigations

By using the Health and Care Act to make a consequential amendment to the NIS Regulations, we will be bringing ICBs into an established regulatory framework that has been functioning effectively for the past three years. For this reason we see the risks of this provision as minimal.

22. Information about inequalities

Policy summary

This amendment requires NHS England to publish a statement setting out a description of the powers available to relevant NHS bodies to collect, analyse and publish information relating to inequalities in access to, and outcomes from, health services. NHS England must also give views as to how these powers should be exercised in connection to this information. The amendment does not require the collection of new or additional information. The amendment is in line with the government's policy priority to level up outcomes and opportunities across communities and geographies (and reflects parliamentary interest in health inequalities).

NHS bodies routinely report and publish performance data and NHS England already issues different types of guidance that NHS bodies are used to receiving and acting on.

The amendment builds on existing work by NHS England to support local systems to identify and take steps to tackle inequalities through, for example, the development of RightCare packs and the Health Inequalities Improvement Dashboard. It also builds on the highly effective approach to data disaggregation employed during the COVID-19 vaccination programme rollout which allowed for greater targeting to increase uptake among groups in society where uptake was low but national-level data showed high levels of coverage.

On a number of key measures, health inequalities have been worsening in recent years and a shift in focus and effort is needed nationally, regionally and locally to bring about improvements. For example, in 2018-20 the absolute gap in life expectancy (LE) at birth between the most and least deprived areas in England was 9.7 years for males and 8.0 years for females. This gap has widened by almost 5 months for males, and 6 months for females since 2015 to 2017 (the most recent non-overlapping period). The inequality in LE at birth, as measured by the Slope Index of Inequality (SII), has significantly widened for males by 0.3 years, and females by 0.5 years since 2015 to 2017. The SII in 2018 to 2020 was 9.7 years for males, and 7.9 years for females. According to the Secretary of State's annual report 2020-21, of the eleven inequalities indicators analysed, six have shown a statistically significant widening of inequality from their baseline time period.

The government published its landmark levelling up White Paper in February in which it announced the publication of a Health Disparities White Paper later this year. These publications point to the need for new approaches, supported by evidence driven by data.

The amendment is consistent with the NHS Long Term Plan which directs systems to develop more accurate and timely datasets to support evidence-based interventions. Similarly, the NHS 2022/23 priorities and operational planning guidance asks systems to

focus on 10 priorities one of which is: *Continue to develop our approach to population health management, prevent ill-health and address health inequalities – using data and analytics to redesign care pathways and measure outcomes with a focus on improving access and health equity for underserved communities.*

The guidance also states: “Improved data collection and reporting will drive a better understanding of local health inequalities in access to, experience of, and outcomes from healthcare services by informing the development of action plans to narrow the health inequalities gap. Integrated Care Boards, once established, and trust board performance packs are therefore expected to be disaggregated by deprivation and ethnicity.”

Local health systems will take a lead role in tackling health inequalities by building on the [Core20PLUS5](#) approach in 2021/22. The safe and effective use of data is key to this. Systems are asked to develop by June 2022 to put in place systems, skills and data safeguards that will act as the foundation for this. [Planning guidance](#) sets out that by April 2023, every system should have in place the technical capability required for population health management, with longitudinal linked data available to enable population segmentation and risk stratification, using data and analytics to redesign care pathways and measure outcomes with a focus on improving access and health equity for underserved communities.

The relevant NHS bodies will have to set out in annual reports how far they have exercised their functions consistently with NHS England’s views set out in the latest statement. This amendment is one of a number requiring additional content in the annual reports of various NHS bodies but on its own should not impose additional burdens.

Costs

This policy does not require or envisage the collection of new data, and any additional costs from the policy have not been quantified. This is because:

- It is not possible to make an accurate estimate of the costs for the production and dissemination of NHS England’s statement as NHS England has not, at this time, determined or tested the extent of the statement. Discovery work will be undertaken by NHS England to define how extensive the statement should be. Until that is complete the resources required cannot be accurately stated.
- NHS England is already able to issue advice and guidance to various NHS organisations, including on improving data collection and reporting.
- NHS England already has the role of assessing, annually and including this in its annual report, how effectively CCGs have discharged their health inequalities legal duties.

There may be ongoing costs for NHS bodies to comply i.e. to report on the extent to which they have exercised their functions consistently with NHS England’s views, although annual reporting requirements in relation to health inequalities already exist. It is the intention to minimise any costs.

This amendment applies only to NHS organisations and so we do not expect any costs to fall to private businesses.

Benefits

This amendment aims to bring about the following key benefits:

- aid accountability and transparency with consistent presentation of information relating to health inequalities across NHS organisations

- bring a more consistent focus on reducing health inequalities to planning and priorities through improved collection, reporting and monitoring of data
- review action taken, including assessment of impact on reducing inequalities

Efforts to better understand health inequalities, which encourages action to be taken to reduce them supports the Department of Health and Social Care's core mission to enable everyone to live more independent, healthier lives, for longer.

Risks and mitigations

The statement needs to be wide-ranging to be comprehensive, as to cover the activities of different types of NHS organisation. Different NHS organisations may collect data using different collection powers depending on the organisation type and the function which the information relates to. This may mean organisations are unsure which of the views expressed by NHS England they need to comply with, leading to familiarisation costs with the policy.

This risk is considered to be low as NHS England is used to issuing various pieces of guidance, advice, instruction or direction to NHS organisations on complicated and wide-ranging issues. In turn organisations are used to receiving, interpreting and acting on them. However, if necessary, organisations could be supported through mechanisms such as FAQs or a series of webinars both of which are regularly used in training methods employed by NHS England. In addition, NHS England may carry out some advance communications to help organisations to prepare.

A second risk is that NHS organisations do not have the capacity or expertise in data analysis to comply with the statement. This risk is considered to be low because systems are already encouraged to work together to share data and analytical capabilities as stated in the priorities and operational planning guidance and in line with priority 7 (G) referenced above. In principle, therefore, capability and capacity is already being considered and steps being taken to improve where necessary.

23. Further embedding research in the NHS

Policy summary

The Act places a duty on each ICB through section 14Z40 that it “must, in the exercise of its functions, promote (a) research on matters relevant to the health service, and (b) the use in the health service of evidence obtained from research”. This mirrors the existing research duty on Clinical Commissioning Groups, which the Act will remove from the NHS Act 2006. The NHS Act also places similar duties to promote research and the use of research on NHS England and the Secretary of State for Health and Social Care, which will remain.

The Government tabled amendments to make a number of changes to clarify and elevate research duties, along with consequential changes, with the aim of further embedding research in the NHS:

- a) Amending the wording of the ICB research duty so it reads that each ICB must “facilitate or otherwise promote research”, rather than only “promote research”. The intention is to highlight “facilitation” as the more active end of the spectrum of activities meant by “promoting” research, while retaining the breadth of a duty to “promote” research, so as not to narrow the range of the duty. This is a clarificatory change but in doing so the aim is that all ICBs will more actively promote and facilitate research and the use of research, increasing the amount and quality of research in the NHS.

- b) Similarly amending the wording on the NHS England and Secretary of State research duties, so they are a duty to “facilitate or otherwise promote research”, rather than only “promote research”. This avoids inadvertently suggesting that it is not also part of NHSE’s and SofS’s role to facilitate research. These are minor and technical amendments that are consequential on the change to the ICB research duty.
- c) Amending the existing requirements in the Bill as introduced for NHS England to conduct an annual performance assessment of each ICB so that the assessment must in particular include an assessment of how well the ICB has discharged its research duty. This will provide a clear mechanism to identify where ICBs are not satisfactorily exercising their research duty and are not playing their role in embedding research in the NHS. This can help identify and address variation in research activity across the country.
- d) Amending the existing requirements for NHS England business plans, which they must prepare each year, so that they must in particular explain how NHS England proposes to discharge its research duty. This is to ensure that promoting and facilitating research are – and are seen to be – a core part of the work of NHS England. It will also increase transparency of how NHS England plans to discharge its research duty as its business plan must be published.
- e) Amending the existing requirement for NHS England annual reports, so that they must in particular contain an assessment of how well NHS England discharged its research duty to further improve transparency and drive consideration of the research duty. These annual reports must be laid before Parliament.
- f) Amending the existing requirement in the Act for ICBs to prepare a joint forward plan with its partner NHS trusts so that these plans must, in particular, explain how the ICB proposes to discharge its research duty, and other duties. This is intended to help level up the consideration of research across ICBs, to the end of further embedding research and the use of research in the NHS.
- g) Amending the existing requirement in the Act for ICBs to prepare an annual report so that these must in particular explain how the ICB has discharged its research duty, and other duties.

Informed research helps to improve healthcare and health outcomes, and has benefits for NHS staff and the wider economy. Integrated Care Boards will play a leading role facilitating and enabling research in the NHS through their commissioning and other functions. 100% of Trusts in England are research-active⁵⁷, however there are variations in the level of research activity across Trusts. Overall, the provisions aim to level-up research activity across the country to further spread the benefits of research as we move from CCGs to ICBs, building on the progress made by many CCGs.

Other policy options considered

The existing ICB research duty in the Act is deliberately broad and wide-ranging. It encompasses a range of actions, including facilitating and enabling research, such as when ICBs exercise their commissioning functions. In considering clarifying and elevating the wording of the ICB research duty we considered a wide range of alternatives and found none that would capture the existing broad range of activity ICBs could perform to discharge their

⁵⁷ NIHR Clinical Research Network Annual Statistics <https://www.nihr.ac.uk/about-us/what-we-do/our-research-performance/annual-statistics.htm>

duty. It would be detrimental to remove the word “promote” from the duty and replace it with a term which would narrow the research duty to a more restrictive or smaller number of actions.

The changes made to require consideration of the research duty in planning, performance assessment and reporting form part of existing planning, performance assessment and reporting requirements. DHSC considered a requirement for a separate research planning and reporting for ICBs and NHS England, however we considered that creating a new mechanism would risk research being considered as an ‘add on’, instead of central to the work of ICBs and NHS England. Furthermore, the creation of an additional planning and reporting mechanism would have created additional costs on ICBs and NHS England as they would have required further staff time.

Costs

The actions ICBs could undertake to discharge their research duty more actively require time investment from ICB members and staff, such as considering whether providers are research-active when commissioning services. Other actions may also require some monetary investment, such as setting up a dedicated research office or directly commissioning research. However, ICBs will have discretion in how they discharge their research duty. The effect of this further activity to facilitate or otherwise promote research is intended to increase the amount and quality of research in the NHS and there are staff time and resource implications of increased research activity in the NHS.

The change to the wording of the research duties of NHS England and the Secretary of State are minor; both already undertake a range of activity that constitutes facilitation of research.

Preparation of the ICB annual reports and joint forward plans, and NHS England business plans and annual reports, will require some investment of time from ICB members and employees, and from members, employees and others from partner NHS organisations and NHS England. A specific requirement for these reports and plans to include consideration of the research duty may involve increased ICB, NHSE and partner organisation staff time in preparing the reports, however these are likely to be relatively small opportunity costs as no additional staff will be employed to undertake this work. The intention of this focused consideration on the discharge of the research duty is intended to prompt further action to embed research in the NHS.

We expect the additional costs due to the planning and reporting requirements to be low. This is because the existence of the ICB research duty already prompts ICBs, trusts and NHS England to undertake some discussion, information gathering etc to ensure activity takes place to discharge the duty. The planning and reporting requirements will for the large part ensure formal and transparent reflection and publication of that activity and consideration that would have occurred or is already occurring without this change in the legislation. The discharge of the research duty can already be included in existing planning and reporting mechanisms without a new, specific requirement to do so. Furthermore, the costs of a requirement to include discharge of the research duty in the existing planning and reporting mechanisms is lower than if such information was required as part of a wholly separate planning and reporting processes, as discussed above.

The Bill as introduced already included an annual performance assessment of ICBs by NHS England, which is drafted broadly so that it can include assessment of ICBs’ discharge of their research duty, but did not require it. The amendment to require an assessment of the discharge of the research duty may therefore involve require NHS England to spend time

considering and assessing this area, but the research duty may have been included in the assessment without the specific requirement do so.

Benefits

The expected impact of the provisions are to level-up research activity across the country to further spread the benefits of research, including benefits for health outcomes, NHS staff, and the wider economy, as outlined below. The expected impact of not making this change is that some areas of the country would continue to see less research activity and an environment less conducive to the benefits of participation in research and the use of the findings from research.

Patients who are admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication⁵⁸. Evidence has also shown that hospitals which are more research active have lower mortality rates and produce overall better patient outcomes⁵⁹ ⁶⁰. Therefore, we expect the impact of levelling up research activity across the NHS to be better patient outcomes.

Research improves the efficiency of healthcare and can save the NHS and the health and care system more widely, multiples of the cost of the research itself. Research also has a wider positive economic benefit. In England the National Institute for Health Research (NIHR), alongside other networks, support the NHS to deliver research across the country. The NIHR provides the staff, facilities, training and technology that enables research to thrive. For every £1 the government spends on research and development via the NIHR, it generates over £19 in total economic returns⁶¹. Some benefits are realised rapidly, through public expenditure on research attracting further private research spend, while others such as direct health benefits are longer term.

Through the NIHR, the Government funds the 'Clinical Research Network' (CRN), the bulk of which is a cadre of 11,000 research nurses and other health professionals and clinical research delivery specialists that recruit and treat study participants in every NHS trust in England. Commercial research conducted within the NIHR CRN in the years 2016/17 to 2018/19 generated a total of £8 billion of gross value added (GVA) to the UK economy and generated over 47,000 Full Time Equivalent (FTE) jobs. Over that same period, for each patient recruited onto a commercial trial supported by the NIHR CRN, on average NHS providers in England received an estimated £9,189 from life sciences companies, and on average saved an estimated £5,813 per patient (where trial drugs replaced the standard treatment)⁶².

⁵⁸ Jonker, L., Fisher, S.J. and Dagnan, D. (2019) Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication: Results from a retrospective cross-sectional study. *Journal of Evaluation in Clinical Practice*. 26 (1) pp. 203–208. <https://doi.org/10.1111/jep.13118>.

⁵⁹ Jonker, L. and Fisher, S.J. (2018) The correlation between National Health Service trusts' clinical trial activity and both mortality rates and care quality commission ratings: a retrospective cross-sectional study. *Public Health*. 157 pp. 1–6. <https://doi.org/10.1016/j.puhe.2017.12.022>.

⁶⁰ Ozdemir, B.A., Karthikesalingam, A., Sinha, S., et al. (2015) Research Activity and the Association with Mortality Chalmers, J.D. (ed.). *PLOS ONE*. 10 (2) p. e0118253. <https://doi.org/10.1371/journal.pone.0118253>.

⁶¹ Saving and Improving Lives: The Future of UK Clinical Research Delivery <https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery/saving-and-improving-lives-the-future-of-uk-clinical-research-delivery>

⁶² KPMG (2019) Impact and value of the NIHR Clinical Research Network https://www.nihr.ac.uk/documents/partners-and-industry/NIHR_Impact_and_Value_report_ACCESSIBLE_VERSION.pdf

Evidence shared with the Health and Care Bill Public Bill Committee also showed there is a strong body of evidence which shows that engaging in research improves job satisfaction⁶³ amongst health workers, boosts staff morale and can reduce burnout⁶⁴.

Given the high return on investment of research, we expect the overall benefits of the outcome of increased research activity and the use of evidence from research to vastly outweigh the costs. As the research planning, reporting and assessment are integrated within existing requirements, we expect the administrative burden to be minimal.

Risks and mitigations

There is a risk that ICBs, as a new body, will be unsure how to fulfil their research duty to facilitate or otherwise promote research. We expect this risk to be low given the existing promotion of research in Clinical Commissioning Groups and the strong support available to ICBs from DHSC, NIHR and NHS England. The requirement in the Act for NHS England to publish guidance for ICBs on the discharge of their functions mitigates this risk. Furthermore, there is an amendment which will require ICBs to keep under review the skills, knowledge and experience that it considers necessary for members of the board to possess in order for the board effectively to carry out its functions, and take such steps as it considers necessary to address or mitigate that shortcoming. This further mitigates risks around the expertise needed to exercise the research duty.

NHS England may be unclear how to conduct performance assessments on ICBs with regard to the research duty, as ICBs will be a new body. However, the Secretary of State may issue guidance for the purposes of these performance assessments, which the Act would require NHS England to have regard to, which could mitigate this risk.

24. ICB and NHSE inequalities duty extension

Policy summary

This provision extends part of the duty on NHS England and ICBs to have regard to the need to reduce inequalities in access to, and outcomes from, health services. Specifically, where NHSE and ICBs must have regard to the need to 'reduce inequalities between patients with respect to their ability to access health services', this amendment to the Act changes 'patients' to 'persons'⁶⁵.

The amendment is in line with government policy to level up outcomes and opportunities across communities and geographies and reflects parliamentary interest in health inequalities.

People in Inclusion Health⁶⁶ groups and people experiencing health inequalities often face barriers to accessing health and care services. For example, a mystery shopping exercise conducted by Friends, Families and Travellers in March - April 2021 found that 74 out of 100

⁶³ Wenke, R.J., Mickan, S. and Bisset, L. (2017) A cross sectional observational study of research activity of allied health teams: is there a link with self-reported success, motivators and barriers to undertaking research? BMC Health Services Research. 17 (1). <https://doi.org/10.1186/s12913-017-1996-7>

⁶⁴ Shanafelt, T.D., West, C.P., Sloan, J.A., et al. (2009) Career Fit and Burnout Among Academic Faculty. Archives of Internal Medicine. 169 (10) p. 990. <https://doi:10.1001/archinternmed.2009.70>.

⁶⁵ See page 3 line 32 (NHS England) and page 19, line 32 (ICBs) of HL Bill 132 (the Health and Care Bill as amended on Lords Report).

⁶⁶ [Inclusion Health: applying All Our Health - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/inclusion-health-applying-all-our-health)

GP surgeries refused registration to nomadic patients, against NHS guidelines⁶⁷.

Not only does this contribute to poorer outcomes for individuals, the impact on the system and wider population can be significant. One study revealed that people experiencing homelessness in England are 60 times more likely to visit A&E in a year than the general population⁶⁸. This can contribute not only to the significant costs of emergency care, but also the worsening of treatable and preventable conditions and widening of health inequalities. It has been suggested that nearly 1/3 of deaths of people experiencing homelessness are caused by treatable conditions⁶⁹.

The duty under the previous wording requires NHSE and ICBs to have regard to the need to reduce inequalities in relation to patient's ability to access health services. This amendment extends this to 'people', meaning that those who aren't already accessing health and care and are therefore not considered 'patients', are in scope of considerations regarding inequalities in access.

We do not consider that 'patients' includes those not accessing health services. Patients is not defined for the purposes of these duties, but it is elsewhere in the NHS Act 2006, such as section 14Z32 (the duty on ICBs to promote the NHS Constitution). Here, it means persons to whom health services are being provided. As such, we do not consider the previous wording to be sufficient for people not accessing services, including the most vulnerable and people at the sharpest end of health disparities.

In terms of other policy options considered, DHSC explored explicitly naming inclusion health groups on the face of the bill, given they typically face significant barriers to access. However, as 'inclusion health' is not a legally defined term, we would have needed to define and name all groups that could fall under this category, which carried the risk of inadvertently excluding groups that are not named. The groups most at risk from health disparities may vary between different populations and may also change over time; by keeping the definition flexible it allows for bodies to react to their own local and system population's needs accordingly.

We are also pursuing options outside of the Health and Care Act to reduce health disparities via improving access to health and care, including inclusion health groups. This amendment provides a foundation for NHSE and ICBs to have the needs of vulnerable groups in mind when considering inequalities in access.

Costs

The costs associated with this amendment have not been quantified, however we expect the costs would be minimal. The provision extends the population group in scope of consideration, however, the overall duty to consider health inequalities with regards to access to health services exists already.

There may be ongoing costs to comply with this duty i.e., to report on the extent to which they have considered access in relation to health inequalities, although annual reporting requirements in relation to health inequalities already exist so we do not envisage this addition would create significant change or additional burden.

⁶⁷ [Locked-out-A-snapshot-of-access-to-General-Practice-for-nomadic-communities-during-the-COVID-19-pandemic.pdf \(gypsy-traveller.org\)](#)

⁶⁸ [Multimorbidity and emergency department visits by a homeless population: a database study in specialist general practice - PMC \(nih.gov\)](#)

⁶⁹ [A third of homeless deaths are from treatable conditions | UCL School of Life and Medical Sciences - UCL – University College London](#)

By considering people who are not accessing health and care services, costs may arise in responding to identified needs, for example, through the commissioning of specific services such as outreach. However, we expect that this would be picked up within existing budgets and flexible funding pots, through local commissioning processes. This amendment is permissive in nature and does not impose any obligation to deliver specific services.

Where decisions are taken to commission services to improve access to services, this could have an impact via the re-allocation of resources from other areas. However, we know that the cost of health inequalities and multiple disadvantage is substantial – for example, the increased A&E usage amongst vulnerable populations carries a significant cost.

Benefits

On a number of key measures, health inequalities have been worsening in recent years and a shift in focus and effort is needed nationally, regionally and locally to bring about improvements. We expect this amendment will contribute to the government-wide levelling up strategy by reducing health inequalities in places and communities across the country.

It is expected that this amendment will have a positive impact on people who do not access health services, by ensuring that it is not only *patients'* ability to access to health services which must be considered by ICBs and NHSE. We intend for this amendment to lay the groundwork for a better understanding of the needs of Inclusion Health groups at a local level, to better inform commissioning decisions.

Risks and mitigations

It could be argued that the shift from patients to more generic terms, means that any person's access to any health services regardless of clinical need must be considered which may increase the number of people the NHS must consider with respect to inequalities. At present, it is only those who do access health services who are considered with respect to inequalities of access. It is widely acknowledged that access to the 'comprehensive health service'⁷⁰ is based upon clinical need,⁷¹ and the NHS is committed to providing the most effective, fair and sustainable use of finite public funds.⁷² Therefore, we do not believe that the duty would be expanded to this extreme.

There is a risk that this amendment alone won't improve access for people in inclusion health groups and others experiencing health inequalities due to entrenched issues around lack of trust, stigma and other barriers. However, we envisage that this will be a foundation for future action and an important step towards consideration of inclusion health groups in the commissioning of services.

25. Climate change duties

Policy summary

The Act places clear climate change and environmental duties on NHS Trusts, Foundation Trusts, Integrated Care Boards and NHS England. Specifically, the Act compels these NHS

⁷⁰ S.1(1) NHS Act 2006

⁷¹ Principle 2, NHS Constitution [The NHS Constitution for England - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/672222/nhs-constitution-for-england.pdf)

⁷² Principle 6, NHS Constitution

Bodies to have regard to how they can support the attainment of key government climate and environmental ambitions, namely:

- achieving Net Zero carbon emissions in line with the Climate Change Act targets
- preparing for and adapting to the risks posed by climate change
- improving the natural environment, in line with the government's targets set under the Environment Act (2021)

The duties apply to all of the relevant body's functions.

In addition, the duty placed on NHS England enables them to issue statutory guidance to the relevant bodies to assist them in complying with these duties, providing clarity of direction and setting out the required action for key NHS decision-makers.

According to its landmark [Delivering a 'Net Zero' NHS](#) report, as of 2020 the NHS in England was responsible for an estimated 24.9Mt of CO2 emissions. This would equate to around 4% of national emissions. This includes major contributions to the UK's CO2 emissions footprint through the NHS's procurement of goods and services (calculated by NHS England at around 19 Mt of CO2 equivalent). In addition, NHS organisations manage over 25 million square meters of land in acute care alone, supporting key government ambitions on biodiversity, air quality, and waste reduction.

The NHS's interest in tackling these issues is powerful and direct. The climate crisis is without question a health crisis. The [World Health Organisation](#) expects climate change to cause around 250,000 extra deaths per year globally between 2030 and 2050, and health services around the world continue to be on the frontline in dealing with climate impacts.

NHS England has led the way on this agenda, setting [ambitious targets](#) for achieving Net Zero for direct emissions by 2040, and for its indirect emissions by 2045. The UK health systems have also set the standard globally through the COP26 Health Programme, with over 50 countries joining the NHS in committing to develop resilient, low carbon health systems.

Fulfilling these aspirations will require unprecedented, sustained action at every level of the NHS - from Trusts to Integrated Care Boards to NHS England. For this to happen, climate change must become a consideration in every decision the NHS takes, and that means weaving this requirement into the legislative fabric of our health system.

Other policy options considered

The Government's two core pieces of environmental legislation are the Environment Act (2021) and the Climate Change Act (2008). These pieces of primary legislation place direct responsibilities upon central government; they do not, however, extend directly to all NHS bodies.

It is possible that we could simply have captured the spirit of this legislation in non-legislative commitments and contracts. For instance, the Government is already in the processes of embedding environmental objectives in the wider "system architecture" of the NHS – such as the NHS mandate and constitution, and in forthcoming system guidance e.g. the estates planning guidance due to be issued to ICSs.

However, this would not have the same weight as primary legislation, and these options alone would not adequately reflect the seriousness of the climate crisis, or the need for urgent action among NHS bodies.

Conversely, it is possible that we could have gone even further in law by prescribing hard quantitative targets on, for instance, NHS carbon emissions reduction. This, however, would have been an extremely blunt instrument that reduced NHS England's flexibility to set and adjust their own targets considering the Government's national targets; it would also have reduced flexibility to allocate limited NHS resources (particularly capital) to competing demands.

The chosen option of these "have regard" duties strike the right balance between reflecting the seriousness of the climate crisis (and NHS role within it) and ensuring the NHS has sufficient flexibility in how it approaches these issues, and balances them against competing priorities.

Costs

Precise costs and benefits will depend on how meeting this duty is balanced against meeting others. Notwithstanding this, there may be development costs to NHS England in further developing system-wide guidance. This may include behavioural research, data analysis, and user testing. There will also be some familiarisation costs to Trusts and ICBs in understanding and following that guidance.

Based on the current direction of travel set out in the NHS's Delivering a Net Zero Health Service (2020), we have a high degree of confidence that the duty will be used primarily to add weight and urgency to NHS England's commitment to achieve Net Zero direct emissions. For instance, NHS England has already issued non-statutory guidance to Trusts developing local carbon reduction plans, through the development of Green Plans. The substantive effect of the duty, therefore, is to add legal weight to the asks being made of Trusts. The associated costs are expected to be met through a combination of NHS capital funding, and externally available funding, such as BEIS's public sector decarbonisation scheme. As such, immediate actions associated with the duty are expected to be met through existing funding streams, though this may have an opportunity cost as resources are reprioritised within existing budgets to support implementation. As with Net Zero generally (i.e. in every sector, not just the NHS), there are longer term capital costs that will need to be considered through future Spending Review processes.

Benefits

By issuing statutory guidance to relevant bodies on complying with these duties, this should provide clarity of direction and the set out required actions for key NHS decision-makers. Therefore the policy could potentially lead to following benefits:

- reduction in the environmental impact of the NHS and in turn reduce air pollution and improve local environments
- reduce long-term running costs for the NHS through the decarbonisation of NHS buildings whilst increasing energy efficiency – for instance BEIS estimates that the half a billion pounds it is investing in decarbonising public buildings (including £329m

for NHS Trusts) will save an estimated £650m in energy bills every year for the next 15 years⁷³.

- reduction of carbon emissions through the procurement of NHS goods and services.
- Where possible, support attempts to increase species abundance through the management of NHS land.
- Enhanced adaptation of NHS infrastructure and frontline services to the predicted impacts of climate change e.g. heatwaves and flooding.

Risks and mitigations

Any new legal duty brings a risk of litigation, and we are conscious that the government's Net Zero commitments (in particular) have been associated with the risk of legal challenge. NHS England will continue working with the relevant bodies to help them meet the duty, including through the production of green plans and tracking of carbon emissions. Moreover, the duty does not place explicit legal targets on NHS bodies, or otherwise give legal effect to the NHS own environment targets. The duty is framed as one of "having regard" to the government's environmental targets and empowers NHS England to issue statutory guidance to achieve this. Where decisions are taken by any of the relevant bodies not to exercise particular functions with a view to complying with the Climate Change Act or Environment Act, it is expected that the rationale for reaching those decisions would be evidenced. This would further serve to mitigate the risk of a successful legal challenge.

26. Accountability and Transparency of Mental Health Spending

Policy summary

The provision seeks to strengthen the accountability and transparency on decisions and spending relating to mental health. It is split into two parts.

The first part sets out a requirement for the Secretary of State to publish and lay before Parliament each financial year a document setting out whether NHS mental health expenditure - incurred by NHS England and integrated care boards (taken together) - is expected to increase, including the amount and proportion, and provide an explanation. The Secretary of State needs to publish and lay the documents before the start of the financial year to which it relates. It is our intention that this document will be in the form of a Written Ministerial Statement.

The second part of the provision requires both NHS England and the Integrated Care Boards to retrospectively report back on their performance against this expectation as part of their respective annual reporting requirements.

There has been a historic funding and treatment gap for people with mental health needs. Driving clarity and transparency about funding spent on mental health care, as well as increasing the funding for mental health services, are seen as significant aspects of measuring and increasing "parity of esteem" – valuing and treating mental health equally to physical health.

Through its mandate for 2022-2023, NHS England is expected to treat mental health with the same urgency as physical health. This is monitored through three metrics including mental

⁷³ <https://www.gov.uk/government/news/public-building-upgrades-to-save-taxpayers-650-million-per-year>

health services real terms expenditure growth. Under current arrangements, NHS England and NHS Improvement requires that local clinical commissioning groups (and ICBs once operational) meet the 'Mental Health Investment Standard'. This requirement is set out in NHS England planning guidance, and, ensures that local funding for mental health grows at least in line with the growth in their overall funding allocations. Performance against the Mental Health Investment Standard is tracked via the Mental Health Dashboard, which NHS England publish quarterly, and is also reflected in NHS England's annual report.

While these existing measures provide accountability and transparency of mental health spending they are subject to change and are not set in statute.

Costs

There are potential resourcing costs associated with the drafting of the annual Written Ministerial Statement, and the sections on mental health spending in the NHS England and Integrated Care Boards annual reports. However, these are expected to be small and have not been quantified.

Increased accountability and transparency on spending may draw scrutiny on the level of funding for mental health conditions. This may cause the re-direction of spending from physical to mental health, and therefore create opportunity costs for physical health spending. While this may be the case, this policy only requires the setting out of the expectation of NHS mental health spending and the retrospective reporting against this expectation and does not mandate any further actions or decisions on spending. In this regard, this policy allows the government to make cost-effective decisions which are done in such a way as to reflect system priorities.

Benefits

The benefit of this provision is that it will create greater transparency on the expectations for mental health spending and performance in the context of that spending. It will provide a mechanism for Parliament, stakeholders and the public to hold the Department, NHS England and the ICBs to account against the commitment to deliver parity of esteem between physical and mental health.

Increased transparency and accountability around mental health spending may lead to higher spending, and therefore have benefits for people who use services.

Risks and mitigations

The risks associated with this policy are minimal. However, there may be a small risk that in drafting this report, there is an opportunity cost of resources being diverted from other business critical areas.

Annex A: NIHR Policy Research Programme for Health Reform Evaluation

Background

In 2014 the NIHR DHSC Policy Research Programme funded four projects under the Health Reform Evaluation Programme exploring different aspects of the new health and social care system following the Health and Social Care Act 2012. The four projects explored:

- The new NHS commissioning system (led by Professor Kath Checkland, University of Manchester)
- Diversity of healthcare provision

- (led by Professor Rod Sheaff, University of Plymouth)
- The establishment and operation of Health and Wellbeing Boards (led by Professor David Hunter, Newcastle University)
- Commissioning public health services (led by Ms Linda Marks, University of Durham)

Research Outputs

Hunter, D., Perkins, N., Visram, S., Adams, L., Finn, R., Forrest, A. and Gosling, J. (2018), Evaluating the leadership role of Health and Wellbeing Boards as drivers of health improvement and integrated care across England

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Liu D, Mason A, Marks L et al. (2018) Effects of local authority expenditure on childhood obesity. *European Journal of Public Health* doi: 10.1093/eurpub/cky252

Mason A, Liu D, Marks L et al. (2018) Local authority commissioning of NHS Health Checks: A regression analysis of the first three years. *Health Policy*.