Working Paper
Analysis of the Health and Care Bill 2021
Procurement, Payment, Competition and Patient Choice Provisions

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1. What did the White Paper promise?

The White Paper 2021 "Integration and Innovation: working together to improve health and social care for all" published in February 2021 contained a discussion of the legislative proposals for the Health and Care Bill 2021. With an aim of reducing bureaucracy the White Paper promised a reform of the competition law as it was applied to the NHS and of the procurement rules as set out in the Health and Social Care Act 2012 (White Paper, p. 9, point 1.15). With the same aim of reducing bureaucracy "further pragmatic reforms to the tariff" have also been promised (White Paper, p. 9, point 1.15). It also contained proposals for legislation around patient choice as part of a packet of measures which are meant to support collaborative work "in a way that will improve outcomes and address inequalities" (White Paper, p. 31).

Procurement

The White Paper postulates "to remove much of the transactional bureaucracy" accompanying competition and procurement rules in the NHS. In particular, it envisages that "the NHS should be free to make decisions on how it organises itself without the involvement of the Competition and Markets Authority (CMA)" (p. 41). With regards to procurement rules, it proposes to create "a bespoke health services provider selection regime" which will give commissioners greater flexibility and discretion over procurement processes. "Where competitive processes can add value they should continue, but that will be a decision that the NHS will be able to make for itself" (p. 41). At the same time it reiterates the commitment to retaining some form of purchaser provider split – "a division of responsibility between strategic planning and funding decisions on the one hand, and care delivery on the other, but allow for its operation in a more joined up way." The payment regime reforms are meant to support the more flexible work within the system approach (p. 23).

The White Paper commits to removing commissioning of healthcare and public health services "from the scope of the Public Contracts Regulations 2015, as well as repealing Section 75 of the Health and Social Care Act 2012 and the Procurement, Patient Choice and Competition Regulations 2013" (p. 40) "The provider selection regime will be informed by NHS England's public consultation, and aims to enable collaboration and collective decision-making, recognising that competition is not the only way of driving service improvement, reduce bureaucracy on commissioners and providers alike, and eliminate the need for competitive tendering where it adds limited or no value." At the same time the White Paper anticipates a continuing place for "voluntary and independent sector providers" and that NHS will continue to be free at the point of care (p. 40-41).

National Tariff

The White Paper states that rationale for national tariff provisions was partially designed to support payment by activity approach which "may not always best facilitate new payment approaches to support collaboration or support the use of digital tech and services in the provision of care." It postulates that the new payment system supports the direction of travel towards collaboration and integration, removes barriers to desired pricing approaches; and simplifies and streamlines the

pricing process. The legislative proposals include allowing NHS England to specify the national price for a service either as a fixed amount or a formula; to amend provisions of the National Tariff (with appropriate safeguards); to include public health services within the scope of pricing provisions set by NHS England (p. 41). It also proposes to "remove the requirement for providers to apply to NHS Improvement for local modifications to tariff prices" (p. 41).

Competition

The White Paper commits to removing CMA's function to review mergers involving NHS foundation trusts, removing NHSI's specific competition functions and its general duty to prevent anti-competitive behaviour, removing the need for NHS England to refer contested licence conditions or National Tariff provisions to the CMA (p. 39-40). It posits that NHS England "as overseer of the system" will have powers to review NHS transactions "to ensure that decisions can always be made in the best interests of patients" (p. 39).

Patient Choice

The White Paper makes a commitment that "a patient's right to choose where and who will provide their health and care needs will be preserved and strengthened in the new system arrangements" (p. 38). The patient choice in conjunction with using private sector capacity is seen as a tool to improve waiting times and patient experience of services. The White Paper makes a commitment to preserving the existing patient choice rights as set out in the current legislation as well as "bolstering the process for AQP arrangements". It mentions a duty to protect, promote and facilitate patient choice imposed on bodies which will commission clinical healthcare services. It also posits that ICSs "can be powerful drivers of patient centred approaches that provide greater choice and control to patients by transforming services around the specific needs of their populations" (p. 38). Finally, there is a commitment to reducing "the health inequalities currently experienced in the area of choice" by raising clarity and awareness of patient choice rights and "of the range of choices available" (p. 38).

2. What is being proposed in the Bill?

The Health and Care Bill 2021 proposes a number of amendments to the existing legislation, including the Health and Social Care Act 2012 and the National Health Service Act 2006, governing procurement of clinical services, provider competition, patient choice, commissioning responsibilities and payment regime in the English NHS.

Procurement of clinical healthcare services

The Bill proposes to revoke Sections 75 to 78 and Schedule 9 of the HSCA 2012 and the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013 (Clause 68 & 69 of the Bill). Although complex and allowing some exceptions, these provisions in essence suggested that competitive tendering is to be a preferred method of procuring clinical services (Osipovic et al. 2019). The rationale for repealing these provisions is "to reduce bureaucracy on commissioners and providers alike, and reduce the need for competitive tendering where it adds limited or no value" (Explanatory Notes (EN) to the Bill, Bill 140–EN, p. 115).

The amendments apply "for NHS and public health service commissioners when arranging clinical healthcare services e.g., hospital or community services" (EN, point 114). The procurement of non-clinical healthcare services (e.g. consumables, professional services etc.) is out of scope of these

amendments. However, the Bill establishes a "provision for mixed procurements in the regime, where a contract involves a mixture of health care and other services or goods, for example if a health service is being commissioned but in the interests of providing joined up care some social care services are also commissioned as part of a mixed procurement" (EN, point 114). This is done by a means of an amendment to the National Health Service Act 2006 extending the scope of the procurement regulations to the procurement by a "relevant authority" of "(a) health care services for the purposes of the health service in England, and (b) other goods or services that are procured together with those health care services" (Clause 68 of the Bill). Thus the amendments will also apply to the mixed procurements. The "relevant authority" means "(a) a combined authority; (b) an integrated care board; (c) a local authority in England; (d) NHS England; (e) an NHS foundation trust; (f) an NHS trust established under section 25" (Clause 68 of the Bill).

The Bill does not amend an application of the Public Contracts Regulations 2015 (PCR 2015) to the procurement of clinical healthcare services. The PCR 2015 stipulate that the procurement of clinical health services above a certain contract value[1] imposes certain conditions on commissioners such as a requirement to advertise contract opportunities (on a 'Find a Tender' platform)[2], follow a transparent procurement process, publish award notices and include standstill periods (Osipovic et al. 2019; Procurement Policy Note 08/20 'Introduction of 'Find a Tender''). Following UK's exit from the EU, the UK has become a standalone member of WTO Government Procurement Agreement, which impacts some aspects of domestic procurement regime as set out by the PCR 2015, including the value of thresholds (see e.g. https://www.anthonycollins.com/newsroom/ebriefings/public-procurement-post-brexit/).[3] The Explanatory Notes state that "the Bill provides a power to create a separate procurement regime for these services, which will include removing the procurement of health care services for the purposes of the health service from scope of the Public Contracts Regulations 2015" (EN, p. 29). However, it is not clear when, where and how the procurement of

[1] The application of value thresholds depends on a type of contracting authority and a type of contract. Currently, the general threshold for service contracts issued by central government authorities is £122,976 and for service contracts which fall under a so called Light Touch Regime procurement is £663,540. There has been some debate as to which thresholds apply to which NHS bodies (https://www.hempsons.co.uk/news-articles/new-procurement-thresholds-will-apply-from-january-2020/). According to Hempsons, the amended regulations (SI 2021 No. 573, The Public Procurement (Agreement on Government Procurement) (Amendment) Regulations 2021) which come into force on 16 August 2021 clarified that the lower threshold (currently set at £122,976) applies to the NHS bodies such as NHS England, NHS trusts and FTs and NHS Business Services Authority. "The flexibilities NHS England and Foundation Trusts currently have as sub-central contracting authorities will also no longer apply from 16 August 2021. The position is unchanged for NHS Trusts, who were already classified as Central Government Authorities." (https://www.hempsons.co.uk/news-articles/foundation-trusts-and-nhs-england-will-need-to-apply-a-lower-procurement-threshold-from-16-august-2021/). It is not clear whether the ICBs will be classified as 'central government authorities' and thus which thresholds will apply to their procurements.

[2] Concurrently, the Procurement Policy Note 07/21 'Update to Legal and Policy requirements to publish procurement information on Contracts Finder' removed a requirement on NHS bodies to publish low value contract notices for clinical healthcare services on a 'Contracts Finder' platform (https://www.hempsons.co.uk/news-articles/new-ppn-published-update-to-legal-and-policy-requirements-to-publish-procurement-information-on-contracts-finder/).

[3] "The GPA is a plurilateral agreement within the World Trade Organisation framework between many of the major international economies, including the US, Canada, the EU and Japan. Prior to leaving the EU, the UK participated in the GPA as an EU Member State. The UK acceded to the GPA as of 1 January 2021 in its own right, i.e. from the end of the Implementation Period." The WTO GPA opens up procurement markets to the members of GPA (subject to bilateral trade agreements). The UK must comply with the obligations under GPA to avoid legal challenges, financial penalties and "reputational damage" (Explanatory Memorandum To The Public Procurement (Agreement On Government Procurement) (Amendment) Regulations 2021, SI 2021 No. 573, p. 2).

clinical healthcare services will be taken out of PCR 2015. Thus the PCR 2015 remain in force and the procurement of clinical healthcare services remains in scope of those regulations for the time being (see e.g. https://www.hempsons.co.uk/news-articles/does-anything-change-in-terms-of-your-procurement-law-obligations-on-1-january-2021-and-what-does-the-future-of-nhs-commissioning-hold/).

In a separate legislative development the PCR 2015 may be amended and replaced by Cabinet Office procurement reforms (EN, point 116, p. 29). The MoU on delegated powers states that "a Cabinet Office procurement Bill will most likely follow this [Health and Care] Bill through passage, which may alter existing legal procurement frameworks. Retaining flexibility in the implementation of this regime will also allow any changes to procurement law introduced by that Bill to be taken account of." (Memorandum from the Department of Health and Social Care to the Delegated Powers and Regulatory Reform Committee (MoU), Health and Care Bill, p. 89).

The consultation on a new framework for the Provider Selection Regime was published by NHSEI in February 2021 (NHS Provider Selection Regime, Consultation on proposals, NHSEI 2021 https://www.england.nhs.uk/wp-content/uploads/2021/02/B0135-provider-selection-regime-consultation.pdf). It sets out a broad framework for a new procurement regime of healthcare services (NHS and public health) commissioned by NHS bodies (NHSE, ICBs, NHS FTs and trusts) and local authorities.[4] It proposes a new duty on decision making bodies that 'services are arranged in the best interests of patients, taxpayers and the population" (NHS Provider Selection Regime, Consultation on proposals, NHSEI 2021, p. 5). The central requirement is that of transparency (p. 6). It outlines three scenarios that decision-making bodies may face with regards to procurement decisions – (1) a continuation of arrangement with the existing provider without competitive tendering, (2) selecting a provider for a new service or where service has changed substantially without competitive tendering on the basis of a direct award, and (3) selecting a provider by running competitive procurement (p. 6). The new regime sets five key criteria – quality (safety, effectiveness and experience) and innovation; value; integration and collaboration; access, inequalities and choice; service sustainability and social value (p. 14) – which have to be considered when making the commissioning decisions (p. 6). However, it proposes that it will be down to the decision making bodies to "prioritise and balance" the criteria as they see fit (provided they are mindful of principles of public law and their relevant statutory duties) rather than follow "any central hierarchy of importance" imposed on these criteria (p. 14). There are no financial thresholds envisaged for the operation of the new regime (p. 14).

There are also some steps envisaged to provide for transparency and scrutiny of decisions and to allow for challenge such as a requirement to publish contract award intention notices allowing other potential providers to make representations, provide justification that they selected "the most suitable provider", demonstrate that they have considered other potential providers. Moreover, the decision making bodies will have to publish a list of contracts awarded, keep a record of their considerations, monitor compliance via internal annual audit and include a summary of their contractual activity in their annual reports. In terms of available remedies, the interested providers will be able to make representations to the decision making body once it has published its decision and/or apply for a judicial review. The consultation proposes to remove the right to legal challenge under the PCR 2015 and via Monitor/NHSI under the PPCCR 2013 (p. 20). If the decision making body

[4] Out of scope of this framework are social services, services not arranged by NHS and LAs bodies (e.g. those arranged directly by SoS such as Test and Trace), non-clinical services, procurement of goods and medicines and community pharmaceutical services (NHS Provider Selection Regime, Consultation on proposals, NHSEI 2021, p. 8).

receives representations objecting to the process following publication of intention of contract award notice, it must discuss the issue with the provider(s) and publish a response to the objection justifying their decision to either reconsider the process and decision or award the contract as intended (p. 21).

The new framework makes competitive tendering a last resort option when it is not possible to identify the most suitable provider without running a competitive procurement process. The document emphasises that the framework “must be applied even-handedly irrespective of the type of provider” (p. 12). Thus decision making bodies will be able to award contracts to private and third sector providers on a basis of direct awards, without running competitive procurement process.

The outcome of the consultation on the proposed provider selection framework has been published in July 2021 (NHS provider selection regime: response to consultation, NHSEI 2021). It remains to be seen which provisions of this framework and in what detail will be made statutory. The consultation document envisages that the new framework will be introduced through a combination of primary and secondary legislation and set out in statutory guidance (p. 5).

The Bill confers a power on the Secretary of State to publish regulations governing procurement of healthcare services and a power on NHS England to publish statutory guidance about compliance with these regulations. “Before publishing this guidance, NHS England must obtain the approval of the Secretary of State (new section 12ZB(6))” (MoU, p. 88-89).

NHS Payment Scheme

The Bill proposes to replace the national tariff regime with the new NHS Payment Scheme (Clause 66 of the Bill). Explanatory Notes stipulate that the rationale for replacing the national tariff with the NHS Payment Scheme is “to give the NHS more flexibility in how tariff prices and rules are set, to help support the delivery of more integrated care at local levels” (EN, point 26 and 27, p. 14). The notes further stipulate a possibility that “there may not be any national tariffs”. The new scheme must be published by NHSE, following a mandatory consultation process with Integrated Care Boards as commissioners and “each relevant provider” including non-NHS providers (Schedule 10 of the Bill).

“The NHS payment scheme will set rules around how commissioners establish prices to pay providers for healthcare services for the purposes of the NHS, or public health services commissioned by an ICB or NHS England, on behalf of the Secretary of State (known as section 7A and section 7B services)” (point 27 of EN, p. 15). Schedule 10 of the Bill amends HSCA 2012 and outlines the principles which will underpin the NHS Payment Scheme replacing “the national tariff (see section 116)”. The Bill states that “NHS England must publish a document, to be known as “the NHS payment scheme”, containing rules for determining the price that is to be payable by a commissioner" "(a) for the provision of health care services for the purposes of the NHS; (b) for the provision of services in pursuance of arrangements made by NHS England or an integrated care board in the exercise of any public health functions of the Secretary of State, within the meaning of the National Health Service Act 2006, by virtue of any provision of that Act.” (Schedule 10 of the Bill). The ‘commissioner’ “in relation to a service, means the person who arranges for the provision of the service” (Schedule 10 of the Bill).

The Bill gives NHS England discretion to design the scheme and enforcement powers of direction over commissioners’ adherence to the scheme: “NHS England may direct the commissioner to take steps specified in the direction, within a period specified in the direction— (a) to secure that the failure does not continue or recur, or (b) to secure that the position is (so far as practicable) restored to what it would have been if the failure was not occurring or had not occurred” (Schedule 10 of the

Bill). In setting prices NHS England must have regard to "(a) differences in the costs incurred in providing those services to persons of different descriptions, and (b) differences between providers with respect to the range of those services that they provide." (Schedule 10 of the Bill). Before publishing the scheme NHS England must carry out impact assessment and consultation process with "(a) each integrated care board; (b) each relevant provider; (c) such other persons as NHS England considers appropriate" and publish a consultation notice (Schedule 10 of the Bill). "Relevant provider" means "(a) a licence holder, or (b) another person, of a prescribed description, that provides— (i) health care services for the purposes of the NHS, or (ii) services in pursuance of arrangements made by NHS England or an integrated care board by virtue of section 7A or 7B of the National Health Service Act 2006 (Secretary of State's public health functions)." Schedule 10 of the Bill also contains a detailed procedure on handling objections to NHS Payment Scheme (based on the percentage of objections) and making amendments which do not require a consultation process.

Competition and provider mergers

"The 2012 Act gave Monitor (now operating as NHS Improvement) and the Competition and Markets Authority ("the CMA") formal roles to provide regulatory oversight of competition issues within the NHS. Monitor currently has a concurrent duty to promote competition in the NHS, whilst the CMA has specific functions to investigate mergers between NHS foundation trusts. The CMA can also investigate contested licence conditions should significant numbers of providers and / or commissioners object to them." (EN, p. 29-30; see also Sanderson et al. 2017; Osipovic et al. 2019).

Another key regulatory mechanism which Monitor/NHSI acquired under the HSCA 2012 is provider licencing. Most providers of NHS-funded services such as FTs and independent providers (unless exempt) are obliged to obtain a licence and obey the licence conditions.[5] One of these conditions (Condition C2 – Competition oversight) prohibits the provider from engaging in anti-competitive conduct (such as collusion) where this is detrimental to patient interests (The new NHS provider licence, 14 February 2013, Monitor). Under the HSCA 2012 Monitor/NHSI has powers to take action against suspected breaches of provider licence conditions (Osipovic et al. 2019).

The relevant provisions of the Bill which amend the NHS provider merger and competition monitoring regime are contained in the clauses 26 to 29, 65, 70 to 73, Schedule 5 and 12 of the Bill. These provisions are very detailed and modify multiple legislative acts which cumulatively result in the curtailment of the role of the national competition regulator CMA in regulating NHS provider mergers and putting other limitations on its role with regards to the NHS system. They also abolish Monitor/ NHS Improvement and remove its competition promotion duties whilst transferring the rest of its functions to NHS England. The following explanation of the changes is based on the Explanatory Notes rather than the Bill itself.

Clause 26 abolishes Monitor and transfers some of its functions to NHS England. The Bill proposes to remove Monitor's duty to promote competition rather than transfer it to NHS England. The Bill also removes the CMA's ability to review NHS foundation trust mergers and transfers the power to review mergers of NHS providers to NHS England (EN, p. 29-30). Monitor's ability to refer contested licence conditions and tariff prices to the CMA will also be abolished. "Instead, NHS England will

[5] Exemptions include: "providers not required to register with the Care Quality Commission, unless they provide Commissioner Requested Services; small providers of NHS-funded health care services whose annual turnover from the provision of NHS services is less than £10 million; providers of primary medical and dental services (eg GPs or dentists who do not provide any other NHS services); providers of NHS continuing health care and NHS-funded nursing care (eg care homes who provide no other NHS health care services); and NHS trusts (which will only be licensed upon authorisation as an NHS foundation trust)." (Briefing for commissioners on the NHS provider licence and Commissioner Requested Services, Monitor 2014, p. 3).

make its own decisions on how to operate the licencing regime and the NHS Payment Scheme, in consultation with local leaders." (EN, p. 30) "The CMA will retain its functions in relation to regulating competition within the private healthcare market." (EN, p. 30)

Clause 27 seeks to ensure that the conflicts between regulatory and other functions of NHS England are minimised as NHSE is also captured by its own regulatory regime. "Clause 27 inserts a new section 13SA, 'Minimising conflicts between regulatory and other functions', in the NHS Act 2006. Subsection (2) of this clause introduces this new section 13S, which in turn places a duty on NHS England to minimise the risk of conflict or manage any conflicts that arise between their regulatory functions, as set out in subsection (2) and (3), and its other functions. NHS England will be required to include in its annual report under section 13U of the NHS Act 2006, a statement explaining how it has complied with its section 13SA duty." (EN, p. 74)

"Clause 28 amends section 100 of the 2012 Act. Section 100 allows Monitor (in future, NHS England) to modify standard licence conditions in all providers' licences or in licences of a particular description. Before making such a modification, Monitor must comply with the notice requirements, giving providers affected the opportunity for those notified about the proposed modification to make representations." (EN, p. 74).

Clause 29 abolishes National Health Service Trust Development Authority (the TDA) and transfers its functions to NHS England. It also revokes a number of Orders and Regulations which governed the role of the TDA (EN, p. 75).

Clause 65 creates a new purpose for which licence conditions may be set or modified in the light of the 'triple aim' duty for NHS England, ICBs, NHS Foundation Trusts and NHS Trusts. Clause 65 confers powers on NHS England to set or modify provider licence conditions by inserting provisions into section 96 of the 2012 Act. "This provision will insert new subsection (da) into subsection 96(2) of the HSCA 2012. Subsection (da) creates a further purpose for which to NHS England may set conditions. In section 96 of the Health and Social Care Act 2012 (limits on functions to set or modify licence conditions)— (a) in subsection (2), after paragraph (d) insert—"(da) for the purpose of ensuring that decisions relating to the provision of health care services for the purposes of the NHS are made with regard to all their likely effects in relation to the matters referred to in subsection (2A);"; (b) after subsection (2) insert— "(2A) The matters referred to in subsection (2)(da) are— (a) the health and well-being of the people of England; (b) the quality of services provided to individuals— (i) by relevant bodies, or (ii) in pursuance of arrangements made by relevant bodies, for or in connection with the prevention, diagnosis or treatment of illness, as part of the health service in England; (c) efficiency and sustainability in relation to the use of resources by relevant bodies for the purposes of the health service in England. (Clause 65 of the Bill) . "Relevant bodies" are defined as NHS England, ICBs, NHS trusts established under section 25, and NHS foundation trusts. (Clause 65 of the Bill).

The Memorandum from DHSC on delegated powers states that the powers given to the NHSE with regards to setting the provider licencing conditions are in order to ensure "the Triple Aim duty" (MoU, p. 81). The 'triple aim duty' reflects the policy introduced in the White Paper and is a duty on NHS organisations "to consider the effects of their decisions on the better health and wellbeing of everyone, the quality of care for all patients, and the sustainable use of NHS resources " (EN, p. 17). "This new duty will require organisations to think about the interests of the wider system and will provide common, system-wide goals that need to be achieved through collaboration." (EN, point 44, p. 18). "The MoU states that "this clause does not widen the power substantively; rather it provides that the power may be exercised in such a way that furthers bodies' compliance with a duty that is

being proposed in this Bill, which is clearly necessary in light of the creation of this duty." And that "the procedure for setting or modifying licence conditions will remain the same as it presently is, as provided already in the 2012 Act." (MoU, p. 82)

Clause 70 sets out the remits of the duty on the NHS England to provide regulatory information and assistance to the CMA which the CMA may require in exercising its relevant functions by amending the NHS Act 2006. "Section 13SD, subsection (2) defines regulatory information as information held by NHS England in relation to its functions under section 13SA(2)(a) or (b) of the NHS Act 2006 (which is being inserted by this Bill, and lists NHS England's regulatory functions) or its functions under provisions being inserted into the NHS Act 2006 by this Bill in relation to the enforcement of patient choice and the oversight and restructuring of NHS Trusts (the proposed new sections 6F, 6G, 27A and 27C of the NHS Act 2006). Section 13SD, subsection (2) also defines the CMA's relevant functions as their functions under the Competition Act 1998 and the Enterprise Act 2002, where those functions are carried out by the CMA Board or a CMA group (within the meaning of Schedule 4 to the Enterprise and Regulatory Reform Act 2013)" (EN, p. 107-108).

Clause 71 introduces an exemption to the NHS Act 2006 applying to the mergers of two or more "relevant NHS enterprises" from merger control regime subject to the CMA review under part 3 of the Enterprise Act 2002. Mergers between an NHS enterprise and an enterprise which is not a relevant NHS enterprise (e.g. a private healthcare provider) are still in scope of the merger control regime. Section 72A, subsection (3) defines relevant NHS enterprise as the activities, or part of the activities, of an NHS trust or NHS foundation trust. Section 72A, subsection (2) clarifies that the merger of two or more relevant enterprises (e.g NHS foundation trusts) with an enterprise which is not a relevant NHS enterprise (e.g, a private healthcare provider) is still in scope of the merger control regime. Clause 71 also repeals section 79 of the 2012 Act, which specifies that mergers involving NHS foundation trusts do fall within the scope of the merger regime in part 3 of the Enterprise Act 2002." (EN, p. 107-108). NHS England retains its role as a sector regulator and "will continue to review proposed transactions, including mergers or acquisitions, to ensure there are clear patient benefits" (EN, p. 108).

Clause 72 removes sections 72 and 73 of the HSCA 2012 providing for Monitor's concurrent competition functions with the CMA. Clause 72 also provides for Schedule 12, which contains consequential amendments removing CMA functions relating to competition by amending Company Directors Disqualification Act 1986, Competition Act 1998, Health and Social Care Act 2012, Enterprise and Regulatory Reform Act 2013, Care Act 2014.

Clause 73 transfers Monitor's provider licencing powers to NHS England, extends NHSE's discretion in setting and amending licencing conditions and removes CMA's involvement in licensing. "Clause 73 amends the 2012 Act regarding NHS licencing. The licence contains conditions for providers of NHS services, including NHS foundation trusts and other providers. All NHS foundation trusts and most other providers of NHS services, including independent provider (but not NHS trusts), must hold a provider licence. In particular, subsection (2) removes the need for Monitor/NHS England to obtain the consent of the applicant to include a special condition in the licence, or to obtain the consent of a licence holder before modifying a special condition of a licence. Subsection (3) repeals subsections 6 to 9 of section 100 of the 2012 Act. These sections allow for licence holders to object to amendments to the standard licence conditions and apply certain conditions to Monitor in relation to those objections." "Subsection (4) repeals section 101 of the 2012 Act, which allows Monitor to refer contested licence conditions to the CMA." (…) "Subsection (9) repeals Schedule 10 of the 2012 Act, which sets out the process for Monitor's referrals to the CMA in relation to

contested licence conditions or a contested levy, as the ability to refer to the CMA in these cases is being removed via the repeal of sections 100(6) to (9) and 142 of that Act" (EN, p. 107-109).

Patient Choice

The Bill revokes Sections 75 to 78 of HSCA 2012 which contain provisions governing patient choice. In their place Clause 67 of the Bill introduces an amendment to NHS Act 2006 to insert provisions relating to patient choice.

The EN state that "the Bill will add similar powers including those relating to guidance and enforcement of the 'standing rules' in the NHS Act 2006. The EN to the Bill stipulate that the standing rules regulations "must contain provisions about how NHS England and integrated care boards will allow patients to make choices about their care" and how they will "protect and promote the rights of people to make choices where those rights arise from these regulations or are described in the NHS constitution" (EN, point 605, p. 104).

Clause 67 of the Bill states that "(1A) The regulations must make provision as to the arrangements that NHS England and integrated care boards must make, in exercising their commissioning functions, for enabling persons to whom specified treatments or other specified services are to be provided to make choices with respect to specified aspects of them. (1B) The regulations may make other provision for the purpose of securing that, in exercising their commissioning functions, NHS England and integrated care boards protect and promote the rights of persons to make choices in relation to treatments or other services, where those rights— (a) arise by virtue of regulations under subsection (1A), or (b) are described in the NHS Constitution" (Clause 67 of the Bill).

The Explanatory Notes state that the power to make guidance and enforcement of patient choice will be held by NHS England (EN, point 124, p. 30). The Bill gives NHS England powers of direction over ICBs in terms of enforcement of patient choice. "There are a wide range of choices that people should expect to be offered in the NHS services they use; for example, choosing a GP and GP practice and choosing where to go for your appointment as an outpatient (with some exceptions). The Bill will allow for these, and other aspects of patient choice, to be preserved under the new powers added to the 'standing rules'" (EN, point 125, p. 30).

The Bill introduces a new duty 'of patient choice' on ICBs. The ICBs are obliged "to act with a view to enabling patient choice (for example, by commissioning so as to allow patients a choice of treatments, or a choice of providers, for a particular treatment)" (Clause 19 of the Bill). The Bill outlines the process for monitoring and enforcing such duty by NHSE through the power to direct ICBs. "6G(1) requires NHS England to publish guidance on how it intends to exercise its power to investigate, direct on, and accept undertaking about patient choice from the new 6F and Schedule 1ZA." Schedule 11 of the Bill provides further details on the procedure of undertakings given by ICBs to NHSE with regards to patient choice compliance. "When NHS England is satisfied that an undertaking has been complied with they must issue a 'compliance certificate'" (p. 105, EN). The Bill also outlines an appeal process for ICBs which are not satisfied with the NHSE decision regarding compliance certificates involving an appeal "to the First-tier Tribunal against a decision of NHS England to refuse an application for a compliance certificate. (2) The grounds for an appeal under this paragraph are that the decision was— (a) based on an error of fact, (b) wrong in law, or (c) unfair or unreasonable. (3) On an appeal under this paragraph, the Tribunal may confirm NHS England's decision or direct that it is not to have effect" (Schedule 11 of the Bill, point 6). The Bill also makes a provision that NHSE's annual report must include patient choice regulations and account of monitoring compliance with the duty of patient choice imposed on ICBs.

The Bill does not specify what the patient choice rules are but stipulates that they must be specified by the NHSE and ICBs and enforced by NHSE.

Although neither the Bill nor Explanatory Notes mention explicitly the specific mechanisms by which patient choice will be enabled, the NHS Provider Selection Regime consultation document discusses two types of mechanisms by which patient choice of provider is currently ensured – patient choice of first outpatient appointment and choosing from a list of accredited AQP providers for some non-consultant led services (p. 15). With regards to the former it states that “the legal right to patient choice for first outpatient appointment will also remain in place” (p. 15). With regards to the latter it proposes a “simplification” and strengthening of AQP arrangements to preclude “unnecessary hurdles for some providers to get on the list in the first instance and providers sometimes being removed from a list without justifiable reason” (p. 16). It states that it is currently at commissioner’s discretion as to whether to establish a choice for non-consultant led services through the AQP framework (p. 16). The consultation document with regards to AQP proposes that procurement process should not be used to select the AQP providers. Instead providers will need to demonstrate that they meet certain conditions (such as being registered with CQC, agree to T&Cs of NHS Standard Contract, accept NHS prices, provide assurances on service requirements and reach agreement with local commissioners with regards to referrals and protocols). Once a provider gets on an AQP list it must be offered NHS Standard Contract. Significantly, decision making bodies have no discretion to remove a provider from the list unless provider fails to deliver on standards and service conditions, they also cannot restrict the number of providers on the list (p. 17). However, the consultation documents implies that establishing AQP lists will remain at commissioner’s discretion.

In addition the NHS Provider Selection Regime consultation document proposes to introduce a requirement that ICBs “when contracting with providers, in particular in a lead provider model, ICS Boards should require via the contract that providers themselves enable choice (eg of location/service/team)” (p. 17). Altogether “these requirements should ensure that patients always have the ability to choose the elective care available to them at the point of referral by their GP, irrespective of whether services in their area have been arranged on a lead provider/provider collaborative/ICP contract basis by the decision-making body” (p. 17).

The patient choice is also supported by a general duty on ICBs to enable patient choice (Clause 19 of the Bill) and provider licencing condition (Condition C1- The right of patients to make choices) which remains in place.

3. What are the implications of these proposals?

Procurement of clinical healthcare services

The legal framework for procurement of healthcare services outlined in the HSCA 2012 was increasingly at odds with the policy turn towards collaboration, first mentioned in the NHS Five Year Forward View and expanded in the later policy documents. Many stakeholders called for a reform of the procurement regime to bring it in line with the policy developments. The tension between the policy direction supporting collaborative interorganisational working and the legislative framework enforcing provider competition principles resulted in the limited enforcement of the legal framework by the NHSEI. Instead, the providers were making use of the PCR 2015 provisions to mount legal challenges regarding procurement disputes directly in the court system (Osipovic et al. 2019).

Although the Bill dismantles the old procurement regime imposed by the HSCA 2012 by repealing the existing provisions, it also creates a vacuum of rules as the details of the new procurement regime are still at the consultation stage. Furthermore, the Bill does not repeal or amend the application of the PCR 2015 to the clinical healthcare services. Thus the procurement decisions may still be challenged by providers on the basis of the PCR 2015 as before.

Arguably, the framework for the new provider selection regime as set out in the consultation document paves the way for direct awards to become the dominant commissioning mechanism when procuring clinical healthcare services. The onus then falls on any interested providers to challenge the direct award notices by making representations to the decision making body and via a judicial review route. There have been concerns raised that the transparency requirements underpinning the decision making with regards to contract awards are not sufficiently robust and the routes for challenging not adequate (https://nhsproviders.org/media/691733/nhs-providers-briefing-health-and-care-bill.pdf , p. 23-24).

These provisions have implications for the role of non-NHS providers in the NHS system. The new framework under consultation allows contracts being awarded on a direct award or temporary extension basis to any provider, including private and third sector providers. Moreover, the Bill in its current form does not preclude non-NHS providers from membership of the ICBs, which will become one of the main decision making bodies commissioning clinical healthcare services and awarding such contracts.[6] Previously, some voiced their concerns that competitive tendering offered a route of market entry to private providers who were able to 'cherry pick' services, whilst not being bound by duties to provide more complex, comprehensive and costly care as NHS providers. Arguably, the removing of a requirement for competitive tendering as proposed in the consultation document may solidify the market position of established private providers and may expand the market entry options for new private providers. Although the intention behind 'the most suitable provider' concept underpinning the new proposed procurement regime may be that the NHS providers will be found the 'most suitable' in the majority of the decisions, there is nothing in the legislative framework to ensure this. The response to consultation document reiterated an expectation for "the [provider selection] regime to be applied even-handedly irrespective of the type of provider" (NHS provider selection regime: response to consultation, NHSEI July 2021, p. 40). Furthermore, the routes to challenge any procurement decisions that may go against the interests of some NHS providers became more limited. Thus the scale of private provision of NHS services will depend on the local power configurations, non-NHS providers' embeddedness in the local decision making structures and service provision, and local level lobbying. Such factors as need for additional capacity, profitability and terms of any trade agreements will also impact a degree to which private sector will be able and willing to engage in the provision of the NHS services.

The lack of structural safeguards and transparency in the current proposals raises the prospect of conflicts of interest and undue influence over decision making processes at the local level.

NHS Payment Scheme

The NHS Payment Scheme gives NHS England a wide discretion to set and vary the pricing structures for the purpose of payment for healthcare services. These flexible provisions are possibly consistent with the move away from tariff based payments towards blended and block payment approaches

[6] The recent press reports suggest that the government may bring an amendment to the Bill which would prevent "individuals with significant interests in private healthcare" from membership of the ICBs (HSJ, https://www.hsj.co.uk/service-design/government-moves-to-keep-private-interests-out-of-key-ics-boards/7030925.article , 20 September 2021).

and allow to keep all options open. These provisions also provide a space for local variations in pricing. These changes could have wide ranging implications for the incentives under which providers operate and thus affect the ability of commissioners to use prices as a way of reallocating resources between different types of provider.

Competition and provider mergers

The provisions in the Bill which amend the competition regime in the NHS are more substantive and detailed than those regarding procurement or patient choice, which leave fleshing out the detail to the future regulations. Nevertheless, the Secretary of State retains the power to make amendments to any Bill provisions, including the competition provisions, by secondary legislation, known as Henry VIII powers (MoU, p. 164).

The Bill severs the powers of the CMA to engage in the competition and provider merger regulation in the NHS as set out in the HSCA 2012, undoing the Lansley's reforms in this respect. This move is consistent with a direction of travel since the signing of Memorandum of Understanding between Monitor and CMA in April 2016 with respect to the exercise of their concurrent powers in which CMA acknowledged "the distinctive characteristics of the sector" (Osipovic et al. 2019).

However, the Bill does not go as far as removing the competition principle from the NHS entirely. For instance, the Bill does not remove a provider licence competition condition (Condition C2 – Competition oversight) which prohibits the providers from engaging in anti-competitive conduct (such as collusion) where this is detrimental to patient interests nor any other licence conditions contained in Section 96 of the HSCA 2012. The NHS England also retains its power as a regulator of NHS provider mergers and enforcer of the provider licencing conditions. Furthermore, the non-NHS providers remain an important part of the provider landscape.

The Bill gives NHS England a scope to set new licencing conditions without a need to consult the providers or the CMA. This is justified by the need to adhere to the 'triple aim' rather than due to efforts to harmonise and rationalise the competition oversight framework. The Bill also gives NHS England greater discretion at setting and modifying standard and special licence conditions without the need to obtain a consent of the applicant or by removing an objection route (EN, p. 108). Again, such a setup gives a lot of scope for NHSE as to how it chooses to interpret and enforce the competition principle as governing the organisational behaviour and relationships in the NHS.

Overall, the Bill has moved the governance and enforcement of the principle of competition from the national regulator back to the sole jurisdiction of the sector regulator - NHS England – where it was prior to the HSCA 2012. The enforcement and monitoring of transactions within the NHS once again becomes sector-based rather than a matter of general competition law. Although NHS England has control over the provider mergers and reconfigurations, the proposed Secretary of State intervention powers over the reconfiguration of NHS services may limit the NHS England's space to act in this matter (Clause 38 and Schedule 6 of the Bill). The reconfiguration of NHS services is defined as "a change in the arrangements made by an NHS commissioning body for the provision of NHS services where that change has an impact on—(a) the manner in which a service is delivered to individuals (at the point when the service is received by users), or (b) the range of health services available to individuals" (Schedule 6 of the Bill).

Patient Choice

The framework for enabling patient choice is underspecified. On the one hand a general policy commitment to ensuring patient choice runs through the White Paper, the Bill and the new procurement regime consultation document. On the other hand there is a policy drive to ensure

greater collaboration between a defined set of providers in a particular geographical footprint of ICS serving a particular population. There is a tension between these two policy aims which is not being acknowledged.

The Bill does not specify the scope over which patients will have a choice in their interactions with the NHS services. The NHS England must publish and enforce guidance in this matter. The Bill also imposes a duty on NHSE to share regulatory information with the CMA, including the information which pertains to NHSE's enforcement of patient choice (EN, p. 107, Clause 70 of the Bill). Thus the CMA may retain some role with respect to patient choice enforcement. The ICBs have been put in charge of implementing the duty to enable patient choice. The Bill also provides a route for juridification of disputes over patient choice provisions between NHS England and ICSs with regards to compliance certificates.

Moreover, the proposed provider selection framework implies that one of the mechanisms to ensure patient choice is through strengthening AQP contractual framework which could be used at commissioner's discretion. The previous research evidence suggests that there were a number of issues associated with the operation of AQP contracts as tariff based, supply driven activity (Allen et al. 2016; Osipovic et al. 2017). In particular, commissioners complained about difficulties to control costs or decommission the arrangements. Furthermore, the AQPs have a potential to exacerbate the inequalities of access between different areas and undermine the principle of access based on clinical need. The proposed continuing use of AQP scheme, unless accompanied by a move away from activity based payments, is also at odds with a turn towards block and blended payment methods expressed in the recent NHS England policy documents (https://www.england.nhs.uk/wp-content/uploads/2021/02/Developing_the_payment_system_for_2021-22.pdf) and implied in the NHS Payment Scheme provisions.

Regardless of these tensions at the level of principles and policy, patients on the ground face big barriers in trying to exercise choice in the resource strapped system of the NHS.

References

Allen, P., D. Osipovič, E. Shepherd, A. Coleman, N. Perkins and E. Garnett (2016). 'Commissioning through Competition and Cooperation. Final Report', London: PRUComm, http://blogs.lshtm.ac.uk/prucomm/files/2016/06/Final-report-revised-version-june-2016-final.pdf.

Osipovič, Allen, Petsoulas, Moran (2017). Next Steps in Commissioning through Competition and Cooperation (2016-2017), Additional Report, London: PRUComm. https://prucomm.ac.uk/assets/uploads/blog/2018/03/CompCoop2-addit-report-dec-2017-final-amended.pdf

Osipovič D, Allen P, Sanderson M, Moran V, Checkland K (2020). The regulation of competition and procurement in the National Health Service 2015–2018: enduring hierarchical control and the limits of juridification. Health Economics, Policy and Law 15, 308–324. https://doi.org/10.1017/S1744133119000240

Sanderson M, Allen P and Osipovic D (2017) The regulation of competition in the National Health Service (NHS): What difference has the Health and Social Care Act 2012 made? Health Economics, Policy and Law 12, 1–19, DOI: 10.1017/S1744133116000116 .