Classification: Official

Publication reference: PR1655



Provider licence consultation notice: Part C – impact assessment

27 October 2022

Please note: This statutory notice is made up of three separate documents:

Part A outlines the proposed modifications to the standard conditions of the NHS provider licence, the effect of the changes and reasons for the proposals.

Part B is the proposed NHS provider licence pending consultation response.

Part C contains the impact assessment and starts on page 2.

A six week consultation period will be held from 28 October to 9 December 2022. Representations can be made to NHS England at LINK.

Contents

1. Introduction of impact assessment	2
2. Methodology of impact assessment	
3. Requirements which reflect system working and the new statutory framework	4
Changes which enhance our ability to address quality issues at independent providers of hard to replace services	6
5. Changes which reflect statutory requirements to address climate change	8
6. Technical/regulatory amendments	10
7. Conclusions and next steps	14
Annex A: Proposed changes to the licence conditions	16
Annex B: Legislative changes in the Health and Care Act 2022	18

1. Introduction of impact assessment

1.1 Context

The NHS provider licence was first introduced in 2013 and is held by all NHS foundation trusts (FTs) as well as independent sector providers unless exempt¹. NHS trusts are currently exempt, but the commencement of the Health and Care Act 2022 requires them to be licenced with a date to be confirmed post consultation, likely April 2023.

The provider licence forms part of the oversight arrangements for NHS providers, serves as the legal mechanism for regulatory intervention, and underpins mandated support at our most challenged providers.

The NHS Oversight Framework and the Risk Assessment Framework and Reporting Manual for Independent Sector Providers of NHS Services both set out overall principles, responsibilities and key metrics that are taken into consideration when determining whether to take enforcement action. Enforcement approaches are set out in the Enforcement Guidance.

1.2 Scope of the impact assessment

NHS England has a duty under section 100 of the Health and Social Care Act 2012 (as amended) to carry out an impact assessment (IA) of modifications to the standard licence conditions if we consider the modifications to be a major change. For completeness, this IA will cover all changes to the Provider Licence, apart from those that are simple wording changes or the removal of obsolete conditions.

We propose four categories of changes to the licence: 1) Requirements which reflect system working and the new statutory framework, 2) Changes which enhance our ability to address quality issues at independent providers of hard to replace services, 3) Changes which reflect statutory requirements around climate change, and 4) Technical/regulatory changes to existing conditions and removal of conditions that are no longer relevant.

Please see Annex A for more details.

¹ Exemptions include primary care providers and providers with NHS contracts under £10 million who are not providing CRS

2. Methodology of impact assessment

2.1 Rationale for licence change

NHS Trusts will become licence holders from April 2023 (subject to final regulations) requiring amendments to the current provider licence. The licence has remained unchanged since it was first introduced in 2013 and so we are also updating the licence more broadly to reflect current statutory and policy requirements, including system working and collaboration.

2.2 Evidence base

This IA considers evidence gathered through engagement with impacted stakeholder groups, including three roundtables with company secretaries, ICB chairs and provider leaders. National stakeholder groups including the CQC, NHS Providers, NHS Confederation, HealthWatch, Shelford Group, Independent Healthcare Providers Network and Social Enterprise UK were also engaged.

The IA was further informed by discussions with internal policy teams and existing reports on policy impacts, including the DHSC's IA on the Health and Care Act 2022. We will seek additional evidence on impact through the consultation process.

3. Requirements which reflect system working and the new statutory framework

3.1 Proposed modifications to reflect system working and statutory framework

Proposal summary

System working and collaboration between providers are key to delivering NHS objectives, and the success of NHS trusts and foundation trusts (FTs) will increasingly be judged against their contribution to the objectives of integrated care systems, in addition to their other duties. These proposed modifications aim to further promote and support system working and patient-centred care, in line with national policy expectations and NHS objectives.

These proposed modifications include:

- New co-operation condition outlining expectations on NHS trusts, FTs and NHS Controlled Providers on system working and co-operation to deliver core system objectives.
- New Triple Aim condition reflecting expectations for NHS trusts, FTs and NHS Controlled Providers to consider the Triple Aim and health inequalities in their work.
- New digital requirements reflecting digital obligations through a new condition and an amendment to existing governance condition.
- Amended Integrated Care condition reframing the condition to encourage providers to actively participate in service integration and reduce inequalities.
- Amended Patient Choice condition expanding the condition to reflect the importance of personalised care.
- Removing the Competition condition reflecting the shift in healthcare priorities from competition to collaboration, and the removal of NHS England's statutory duty in relation to competition oversight.

Expected benefits

System working and collaboration within systems is essential to improving outcomes, tackling inequalities, ensuring value for money, and supporting broader social and economic development. These modifications reflect existing statutory duties, or national policy on system working, integration and collaboration. There are two primary benefits to translating these requirements into the provider licence. First, they support more effective delivery of and adherence to these policies by ensuring internal coherence across our legislative, policy and regulatory frameworks. Secondly, these changes will enhance NHS England's ability to intervene and provide support where these requirements are not being met and so provide a more effective way to resolve these issues than alternative legal mechanisms, such as through judicial review.

Expected costs

Providers are already expected to meet these requirements as set out in legislation and guidance irrespective of their inclusion in the licence. While there may be associated costs in meeting these expectations – such as the cost of updating IT to be interoperable, or staff time dedicated to managing system working – these costs relate to meeting policy/legal requirements and will not increase as a result of inclusion in the licence.

Risks and mitigations

As with all new licence provisions, there is a risk to providers of enforcement taking place in circumstances where it may not be justified. We believe this risk is mitigated by our broader approach to oversight and regulatory intervention as set out in the NHS oversight framework and provider enforcement guidance. These documents set out the processes we will follow, as well as our commitment to working constructively with providers and systems to resolve and identify breaches without the need for enforcement action wherever possible.

Any commercial risk to independent providers from the reframed Integrated Care Condition has been mitigated through draft text in the licence which excludes a provider from sharing information if disclosure of information would materially prejudice its commercial interests.

4. Changes which enhance our ability to address quality issues at independent providers of hard to replace services

4.1 Proposed modifications to Continuity of Service **Conditions**

Proposal summary

Historically Monitor2 (now dissolved) has only had oversight of financial risks to continuity of services at independent providers of commissioner requested services (CRS). The first proposed modification to Continuity of Service (CoS) condition 3 introduces standards of 'quality governance' – in addition to the existing standards of financial management and corporate governance – to provide reasonable safeguards against the licence holder being unable to deliver services due to quality stress.

The second modification is to CoS 6; this condition has previously only been applied to CRS providers when Monitor has issued a notice of ongoing concern or risk, which subsequently allows NHS England to appoint people to assist in the management of the licensee's affairs, business and property.

The proposed changes will now allow us to also issue a notice if we are concerned about a CRS provider's ability to continue providing services due to 'quality stress'. This will also expand the condition so that it applies to 'hard to replace' providers in addition to CRS providers.

Expected benefits

These changes will allow NHS England to have a holistic approach to oversight of these providers and services that take into account both finance and quality risks to continuity of services. This is important given these risks are often linked.

These changes will also enable us to act to protect the continuity of services for NHS patients to ensure services are available when needed when independent providers are facing financial or quality stress, including imposing mandated

² Monitor was the sector regulator for health services in England. The organisation was abolished in July 2022 and many of its statutory functions were transferred into NHS England.

support. They will also benefit patients by allowing us to support services that are difficult to replace, and keep those services from closing.

Expected costs

Independent providers already designated CRS and with good quality governance may see incremental changes as quality conversations will happen in parallel to business as usual (BAU) finance conversations. There may be some minimal additional costs for providers that are facing quality stress related to additional oversight, but as noted above these are offset by the need to protect continuity of services for NHS patients.

It is anticipated that most independent providers likely to be designated by us as hard to replace providers will already be providing some services that are commissioner requested and so there will be limited changes to oversight for these providers. However, there may be a small number of additional independent providers brought into oversight by these changes, although BAU monitoring is light touch if providers are financially stable and have good quality governance.

We also intend to work closely with CQC to reduce the burden of reporting by having a risk-based approach that uses CQC intelligence.

Risks and mitigations

Currently, the number of providers who would be designated as hard to replace is not expected to substantially increase the number of providers under CoS oversight. However, if the definition of hard to replace were to change in the future, the number of providers brought under the licence could increase further. These providers would then face the abovementioned costs, and NHS England would need the resources to oversee them.

The framework defining 'hard to replace' and 'quality stress', as well as future changes to them, will be subject to separate consultation(s) to ensure the benefits of approach outweigh the costs.

Changes which reflect statutory requirements to address climate change

5.1 Proposed inclusion of requirements on Net Zero

Proposal summary

Delivering Net Zero is integral to population health and environmental sustainability. Under proposed changes, NHS trusts and FTs will be expected to have regard to guidance on tackling climate change and delivering net zero emissions and take all reasonable steps to minimise the adverse impact of climate change on health. These requirements are set out in the 2022 Act and mirrored in the NHS Standard Contract.

Expected benefits

There are two key benefits from incorporating these requirements into the provider licence. First, it supports effective delivery of net zero by ensuring coherence across our legislative, policy and regulatory frameworks. Second, it enhances NHS England's ability to resolve situations where a trust is not meeting these requirements in a more effective way than the use of alternative mechanisms.

Expected costs

Providers are already expected to meet these requirements as set out in legislation and guidance irrespective of their inclusion in the licence. While there may be costs in meeting these expectations, these costs relate to meeting policy/legal requirements and will not increase because of inclusion in the licence.

Compliance with Greener NHS expectations will be assessed via a governance lens, meaning it will only be enforced when there is a failure of systems or processes at trust level to address Net Zero. It is therefore not expected to increase regulatory or financial burden above what it would take to comply with the legal duty. Further guidance may be published by us under section 13ND to support compliance (climate change guidance).

Risks and mitigations

There is a risk that expectations around compliance with this condition is unclear, increasing the risk of enforcement in circumstances where it may not be justified. However, this risk is mitigated by the fact that every NHS trust and FT now have in place a Board-approved Green Plan, which is aligned with the NHS 2040 & 2045 Net Zero ambitions and exceed the climate duties in the Health & Care Act.

This risk and that of inconsistent/unfair enforcement is further mitigated by NHS England's commitment to enforce in line with the oversight framework which sets out a commitment to work with providers and systems to resolve and identify breaches without the need for enforcement action.

6. Technical/regulatory amendments

A full list of changes included in this category can be found in Annex A. The majority of these are simple wording changes or the removal of conditions that are no longer relevant.

6.1 Proposed modification to Pricing Condition 3

Proposal summary

The proposed modification would mean licence holders would no longer be required to submit assurance reports to NHS England. Instead, licence holders would be required to have processes in place to ensure the accuracy and completeness of costing and associated information collected and submitted to us as per the mandated requirements.

The modification would also require that providers maintain evidence and submit it when required. This is in line with the Approved Costing Guidance. See the consultation document for more details.

Expected benefits

The Approved Costing Guidance is only able to impose the relevant requirements through their inclusion in the licence. In the past, NHS trusts and FTs have reported a high burden from NHS Improvement (Monitor/TDA) sending in auditors to review their implementation of patient level costing, with limited benefits.

This change allows mandated licence holders to agree when to undertake reviews rather than have it imposed upon them. This change will also ensure that issues that affect costing accuracy are identified and addressed in a more timely/routine manner through embedding costing process into internal/external audit processes.

This change also allows us to support licence holders by providing tools for them to ensure the accuracy of data via the mandated requirements and ensure compliance with the expectations in the Approved Costing Guidance. This more accurate data can then be used to improve patient pathways and underpin decisions to support the delivery of high-quality care for patients and ultimately deliver better value for the NHS.

This change further enables us to ensure that licence holders are using the mandated tools and have the required levels of assurance processes in place and maintains a level of audit assurance that Boards require for their own assurance processes. Feedback from several NHS trusts and FTs supports this change because it allows us to work alongside providers on ensuring and using costing data.

This change also allows us to intervene and provide support where standards are not met or are at risk of not being met. Supporting compliance with these updated costing standards ultimately benefits providers, NHS England, and patients.

Expected costs

Providers should already look at the accuracy of their data through means such as internal audit reviews and Service Line Reporting assessments, and these can be updated to cover National Costing requirements. The inclusion of these expectations in the licence should not therefore incur further costs.

If providers do not yet have these systems in place, there will be a cost in updating them and moving to the new assurance process, but this is outweighed by the importance of maintaining accurate data for planning and decision-making. These costs are also insignificant compared to the time taken to prepare and respond to the previous assurance process.

Independent providers have previously not been required to submit costing data and are not currently required to follow the Approved Costing Guidance. Any future policy decision to do so will need to consider any costs associated with following costing guidance, set against benefits to the NHS, and would be subject to consultation.

Risks and mitigations

There is a risk that inadequate or insufficient support is provided by NHS England to licence holders in implementing their own assurance systems. This would result in incomplete or inaccurate data collection and maintenance. However, NHS England is committed to working with licence holders to support the transition.

Furthermore, the explicit linking to the Approved Costing Guidance is expected to support licence holders to understand future plans for mandatory costing data

collections and encourage early discussions on implementation challenges with NHS England.

6.2 Proposed removal of self-reporting requirements

Proposal summary

General Condition 6 (G6) and Foundation Trust condition 4 (FT4) both require licence holders to report on their compliance with a number of licence conditions and legislative requirements. The former requires both independent providers and FTs to self-certify their compliance via a certificate approved by their Directors, while the latter applies only to FTs and requires the production of a Corporate Governance Statement describing past compliance with licence governance standards and to assess their expected compliance in the year ahead.

More details on what these requirements cover and our proposals can be found in the statutory notice of consultation.

We propose removing the requirements for providers to self-certify via certificate and to produce a Corporate Governance Statement (FT4). The effect of the latter change would mean FTs no longer report on future risks around compliance with governance standards. Assessments of past compliance with governance standards would still be captured via separate annual reporting processes.

Independent providers are not bound by the same additional reporting requirements on compliance with the licence. A self-certification requirement equivalent to G6 is expected to be added to the Risk Assessment Framework and reporting manual for independent sector providers of NHS services to ensure independent providers continue reporting on their compliance.

Expected benefits

Removal of these conditions is expected to reduce both duplication and to reduce regulatory burden on providers.

Many NHS trusts and FTs have told us that the self-certification of compliance and assessments of future compliance with governance standards add little value to their internal compliance processes, and as such their removal would be a welcome reduction in duplication (as past compliance with governance standards is already captured through other reporting requirements) and regulatory burden.

We therefore expect that removal of these conditions will benefits boards and organisations by saving them time and associated resources.

Expected costs

While the majority of providers we spoke with support the proposals, a small minority told us they found the Corporate Governance Statements required under FT4 beneficial in focusing organisational attention to compliance and governance processes. However, we note that NHS trusts and FTs would still be required to report on past compliance with governance standards via separate annual reporting requirements.

As noted above we will continue to collect G6 certifications from licensed independent providers through alternate means. This is a continuation of an existing process and is not expected to add any additional costs.

Risks and mitigations

A minority of providers reported that these requirements helped ensured Board time was spent reviewing their compliance with key requirements and associated processes. However, requirements for boards to routinely consider compliance via separate annual reporting processes remain, and evidence of compliance would continue to be considered as part of well-led assessments.

7. Conclusions and next steps

7.1 Summary of assessment

Requirements which reflect system working and the new statutory framework

We do not anticipate any increased costs or burden from reflecting existing policy and statutory duties into the licence. Inclusion in the licence supports delivery and enhances NHS England's ability to resolve situations where the requirements are not being met.

The risk of enforcement in circumstances where action may not always be justified is low and mitigated by our proportionate approach to enforcement/intervention as set out in the NHS Oversight Framework and Enforcement Guidance.

Changes which enhance our ability to address quality issues at independent providers of hard to replace services

These changes allow a holistic approach to oversight, taking both quality and finances into account. They also allow us to ensure continuity of services for patients, and these benefits outweigh potential costs.

While there may be minimal additional costs to providers and NHS England with the introduction of new quality governance standards, many of the providers affected will already be subject to a licence and are likely already designated CRS, so there will be limited changes in oversight.

The risk of a future increase in providers brought under the purview of the licence is mitigated by the fact that providers will be separately consulted on how the new designations included in these modifications are applied.

Changes which reflect existing statutory requirements around climate change

This requirement reflects the statutory duty in the Health and Care Act 2022 and does not place additional requirements on providers. Its inclusion in the licence supports delivery and enhances our ability to resolve situations where the requirements are not being met.

Technical/regulatory changes

The proposed modification to Pricing Condition 3 reduces regulatory burden and reflects standards that providers should already aim to meet, and therefore

providers should not incur further costs through their inclusion in the licence. The proposed removal of self-reporting requirements, which are largely covered through other annual reporting mechanisms, will reduce regulatory burden.

We welcome feedback on whether there is any risk to the loss of the forwardlooking assessment of future compliance, noting at this stage we believe the risks of removal minimal.

7.2 Next steps

NHS England's consultation on these proposed modifications will run from 28 October until 9 December 2022. Submitted evidence will contribute to our analysis of the impact of these proposals and shape the outcome of this consultation. Any comments on this IA would be very welcome and will be considered as part of our process in finalising licence changes through the consultation process.

Annex A: Proposed changes to the licence conditions

Category of Change	Change	Rationale
Requirements which reflect systems working and the new statutory framework	Extension of licence to cover NHS trusts	2022 Act removes NHS trusts' exemption from holding a licence
	New Co-operation Condition	2022 Act strengthens duties to co-operate in NHS Act 2006, and requires NHS bodies to have regard for guidance on co-operation. Aligns with expectations in the Guidance on Good Governance and Collaboration previously consulted on
	New Triple Aim Condition	2022 Act requires NHS trusts and FTs to have regard to Triple Aim duties
	New Digital Requirements	2022 Act requires bodies to comply with any information standards that apply to them. 2022/23 NHS priorities and operational planning guidance includes support to level up digital maturity, and ensure core level of digitisation and infrastructure. This also supports the NHS Long Term Plan to have digitally-enabled care go mainstream
	Removal of Competition Condition	2022 Act removes NHS England's statutory responsibility for competition oversight
	Inclusion of Personalisation and Patient Choice Condition	NHS Long Term Plan commits to implementing the Comprehensive Model of personalised care across the country. Rate of personalised care interventions included in NHS oversight metrics for NHS system oversight framework
	Integrated Care Condition modified to positive obligation	NHS Long Term Plan sets the vision that integration will be central to NHS. 2022/23 NHS priorities and operational planning guidance also focuses on integrating care across services. NHS Oversight framework reinforces the system-led delivery of integrated care. 2022 Act creates Integrated Care Boards, responsible for commissioning and provision of services within Integrated Care Systems
Changes which enhance our ability to address quality issues at independent	Modification to CoS Conditions	Expands criteria for Hard to Replace Providers, and allows NHS England to act and provide support in situations of quality failure where they would have previously been unable to do so

providers of hard to replace services		
Changes which reflect statutory requirements around climate change	Inclusion of Net Zero requirement	2022 Act requires NHS trusts and FTs to have regard to Net Zero
Technical/regulatory changes to existing conditions and removal of conditions that are no longer relevant	Removal of G3	Regards payment of fees; NHS England has never charged fees
	Modification to G4	Regards Fit and Proper Persons, which was consulted on in 2021. In this consultation it was determined the modification was not a major change, and no IA was completed
	Modification to P1	Wording change to link to the Approved Costing Guidance and make the process clearer for licence holders. Does not change what licence holders are mandated to record and submit
	Modification to P2	Wording change to support modifications to Pricing Condition 1, regarding submission of mandated data
	Replacement of 'National Tariff' with 'NHS Payment Scheme'	2022 Act replaces the national tariff with the NHS payment scheme
	Removal of Pricing Condition 5, requiring constructive engagement with CCGs concerning local tariff modifications	The NHS payment scheme removes local modifications
	Wording change throughout licence from 'Monitor' to 'NHS England'	Wording change to reflect dissolution of Monitor and the transfer of duties to NHS England
	Removal of self-reporting requirements in G6 and FT 4	These requirements apply to both independent providers and NHS trusts and FTs. Removing them means licence holders will not have to self-certify against complying with licence conditions, or produce a Corporate Governance Statement; there was mixed feedback from stakeholders on this proposal
	Modification to P3	Approved Costing Guidance requires mandated providers to ensure the accuracy and completeness of their costing processes and outlines submission details

Annex B: Legislative changes in the Health and Care Act 2022

Legislation	Provider Licence Modification
 Health and Care Act 2022: Section 51 This section removes NHS trusts' exemption from holding a licence 	Extending licence to NHS trusts, in addition to foundation trusts and some independent providers.
 Health and Care Act 2022: Sections 29 – 30 This section covers the financial responsibilities of ICBs and partner trusts - they must exercise functions to meet NHS England's financial expectations Health and Care Act 2022: Section 75 This section requires NHS bodies to have regard for guidance on cooperation, and strengthens duties to cooperate in NHS Act 2006 	Co-operation Condition requires NHS providers to co-operate with NHS bodies and Local Authorities for improvement of NHS services and for the development and delivery of system plans and NHS services.
 Health and Care Act 2022: Sections 52, 67 These sections require NHS trusts and foundation trusts to have regard to the duties of the Triple Aim 	Triple Aim Condition requires NHS trusts and foundation trusts to have regard to duties of Triple Aim when making decisions.
 Health and Care Act 2022: Section 95 This section updates the Health and Social Care Act 2012: Section 250, clarifying to whom information standards can apply and that any body to which they apply must comply with them 	The Digital Information Standards Condition requires NHS trusts and foundation trusts to comply with information standards and guidance on digital maturity where they pertain to requirements in the Co-operation or Triple Aim Conditions.

Legislation	Provider Licence Modification
 Health and Care Act 2022: Sections 53 and 68 Requires NHS trusts and foundation trusts to have regard to net zero and environmental targets, and to adapt to predicted impacts of climate change 	The addition to Foundation Trust Condition 4 (now NHS Condition 2) requires NHS trusts and foundation trusts to have regard to guidance on net zero and climate change, and to take reasonable steps to mitigate the impacts of climate change.
 Health and Care Act 2022: Section 77 This section replaces the national tariff with the NHS payment scheme 	This is a wording change, replacing national tariff with NHS payment scheme.
 Health and Care Act 2022: Section 84 This section removes NHS England's statutory responsibility for competition oversight 	Removal of Choice and Competition Condition 2 prohibiting providers from engaging in arrangements which could prevent, restrict, or distort competition.
 Health and Care Act 2022: Section 77 This section replaces the national tariff with the NHS payment scheme. Under the NHS payment scheme, local modifications have been removed. 	Removal of Pricing Condition 5, requiring constructive engagement with CCGS concerning local tariff modifications.

NHS England Wellington House 133-155 Waterloo Road London SE1 8UG

This publication can be made available in a number of alternative formats on request.