

## Health and Care Bill 2021

<b>Lead department</b>	Department of Health and Social Care
<b>Summary of proposal</b>	The Bill draws on the lessons learned from the Health and Care System and its experience of responding to Covid-19 to improve working together and support integration, to reduce bureaucracy and to ensure accountability and enhance public confidence. Three IA documents <sup>1</sup> support the Health and Care Bill proposing enabling powers to the Secretary of State.
<b>Submission type</b>	Impact assessment (IA) – 17/06/2021
<b>Legislation type</b>	Primary legislation
<b>Implementation date</b>	tbc
<b>Policy stage</b>	Final
<b>RPC reference</b>	RPC-DHSC-5082(1)
<b>Opinion type</b>	Formal
<b>Date of issue</b>	6 September 2021

## RPC opinion

<b>Rating<sup>2</sup></b>	<b>RPC opinion</b>
<b>Fit for purpose</b>	The IAs are now fit for purpose after being revised in response to the RPC's initial review notice. The IAs do not provide EANDCB, BNPV or NPSV but give an overall indication of impacts in line with Scenario 2 of the RPC's primary legislation guidance <sup>3</sup> .

## Business impact target assessment

	<b>Department assessment</b>	<b>RPC validated</b>
<b>Classification</b>	Non qualifying provision	Non qualifying provision (at this stage)
<b>Equivalent annual net direct cost to business (EANDCB)</b>	Unquantified	N/A ( <i>further IA(s) in relation to any qualifying provisions to be submitted at secondary legislation stage for EANDCB validation</i> )
<b>Business impact target (BIT) score</b>	N/A	N/A
<b>Business net present value</b>	Unquantified	
<b>Overall net present value</b>	Unquantified	

<sup>1</sup> Health and Care Bill 2021 Core Measures ("the Core IA"), Impact Assessments for Adult Social Care Provisions ("the Adult Social Care IA"), and Impact assessments summary document and analysis of additional measures ("the Additional Measures IA").

<sup>2</sup> The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the [Better Regulation Framework](#). The RPC rating is fit for purpose or not fit for purpose.

<sup>3</sup> <https://www.gov.uk/government/publications/rpc-case-histories-primary-legislation-ias-august-2019>

## RPC summary

<b>Category</b>	<b>Quality</b>	<b>RPC comments</b>
EANDCB	<b>Green</b>	No EANDCB figure is provided at this stage but the IAs now provide a sufficient qualitative assessment of the impacts on businesses. Throughout the IAs the Department makes commitments to producing quantified impact assessments for secondary legislation “as appropriate”, if and when enabling powers are used.
Small and micro business assessment (SaMBA)	<b>Green</b>	For each of the relevant proposals, reference is made to possible impacts on small and micro businesses (SMBs). The Additional Measures IA identifies possible impacts on SMBs of the proposals relating to data sharing, provider selection, medicines registries, hospital food standards, food information for consumers, water fluoridation and reciprocal healthcare arrangements for rest of world countries. The IA would be improved by providing better evidence on the number of SMBs potentially affected.
Rationale and options	<b>Weak</b>	Overall, the IAs provide limited evidence of the need for government intervention but set out clear objectives. The IAs consider several options and explain why alternatives to regulation would not achieve the objectives. However, they should discuss alternatives to regulation and provide a fuller, equally detail assessment of the proposed options.
Cost-benefit analysis	<b>Satisfactory</b>	While few impacts are quantified, the IAs give an overall indication of their magnitude. The Additional Measures IA contains sufficient narrative and provides illustrative examples of what the costs could be. The Adult Social Care IA also provides some monetised costs and benefits associated with the hospital discharge to assess the proposal. The IAs would benefit from more clearly distinguishing between impacts on businesses and on civil society organisations (CSOs).
Wider impacts	<b>Satisfactory</b>	The Core Measures IA commits to assessing wider impacts at secondary legislation stage. The Additional Measures IA makes the same commitment and briefly discusses potential impacts on competition, innovation and trade. The IAs would be improved if they provided some indication of the conditions under which such an assessment might be deemed appropriate and more detail as to types of wider impacts what would be considered.
Monitoring and evaluation plan	<b>Satisfactory</b>	The IAs suggests that a review will take place after 3 to 5 years and explains that the details of a PIR will be set out at secondary legislation stage.

## Response to initial review

In its initial review notice the RPC stated that the IAs must provide an indication of impacts at this stage. The Core IA now includes a qualitative description of the potential costs associated with the data sharing proposal. The Adult Social Care IA now identifies impacts on businesses from the hospital discharge proposals and explains how the market is divided into private and voluntary organisations. The Additional Measures IA now also explains that costs associated with the medical examiners' proposal are not expected to fall on businesses. The Department has also addressed several of the other areas for improvement identified by the RPC.

## Summary of proposal

The IAs state that the Bill draws on lessons learned from the evolution of the NHS and its experience of responding to Covid-19, to introduce measures that aim to improve working together and support integration, to reduce bureaucracy and to ensure accountability and enhance public confidence. The proposed legislative changes in the Bill are divided into three subsets; core measures, additional measures and adult social care provisions. A full list of the proposals is set out in the annex to this opinion.

The Core Measures IA mainly covers changes that seek to support the delivery of the NHS Long Term Plan and strengthen democratic accountability. It also covers proposals that are not in the NHS Long Term Plan such as data sharing. The Additional Measures IA covers proposals that make targeted changes intended to allow the government to support the social care system, improve quality and safety in the NHS, grant flexibility in taking public health measures and implement worldwide reciprocal healthcare agreements. The Adult Social Care IA covers three proposals to support social care.

## EANDCB

The RPC now considers the approach to indicating direct business impacts fit for purpose at this stage, in line with the RPC's primary legislation guidance<sup>4</sup>.

### Core measures

The core measures mainly comprise enabling powers to regulate the public sector; the Core Measures IA states that a monetised assessment of impacts, relating to the provider selection and choice proposals, will be completed at secondary legislation stage. The RPC expects IAs in respect of qualifying regulatory provisions to be submitted for independent scrutiny at secondary legislation stage. At this stage, the core measures likely to have impacts on businesses appear to be collaborative commissioning, data sharing, provider selection and reconfiguration powers.

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<sup>4</sup> <https://www.gov.uk/government/publications/rpc-case-histories-primary-legislation-ias-august-2019>

### **Additional measures**

All additional measures appear to have business impacts, but the Additional Measures IA explains that they mainly consist of enabling powers, which will result in limited changes or will require secondary legislation before impacts arise. Where possible, it does provide indications of costs; these now include reference to familiarisation and training costs as well as data collection/submission costs to private GPs and small hospitals. The RPC expects to see the IAs for any qualifying regulatory provisions relating to these measures.

### **Adult social care provisions**

The Adult Social Care IA explains the costs associated with delayed hospital discharge and discusses the expected benefits to business associated with the proposed changes. It now also includes familiarisation costs and some further narrative around the impacts. However, there is still a lack of evidence to support the assumptions made in this area for example, in relation to additional costs and delays from assessment (once patients have left hospital).

## **SaMBA**

The RPC considers the SaMBA to be fit for purpose. For each relevant proposal, reference is made to the possible impacts on SMBs. The Additional Measures IA states that the proposals relating to data sharing, provider selection, medicines registries, hospital food standards, food information for consumers, water fluoridation and reciprocal healthcare arrangements for rest of world countries may have impacts on SMBs. While the Additional Measures IA does not provide a robust estimate of these costs or details of exemptions, it commits to examining these impacts *“if and when secondary legislation is introduced”* (page 8).

## **Rationale and options**

The RPC considers the rationale and options sections of the IAs to be weak. While the objectives are clear, there is limited evidence on the extent of the problems that the proposed measures are seeking to address and the extent to which they will meet the objectives. This analysis should be provided for all three IAs and should also have regard to changing patterns of demand for health and care services.

The Core Measures IA now provides more detail on the rationale for the provider payments proposal, but it should consider how the market will evolve and provide clarity on how such payments will be determined and the competition, innovation and labour market effects.

The benefits of some of the proposals are implied but not supported by evidence, which weakens the rationale for intervention. For example, the Core Measures IA makes statements such as *“cooperation largely being in the best interests of the health and care system”* (page 23) without supporting them with evidence or considering the costs of mandating such cooperation.

The IAs consider a limited number of options and explain why alternatives to regulation would not achieve the objectives. For example, the Additional Measures IA discusses an alternative to the medicine registries proposal but states that it was not deemed feasible because without a robust system, “*gaps in the data would still remain meaning that the registry would not be able to support safe and effective use of medicines in all patients*” (page 15). The Core Measures IA states that it focusses on the leading options because of the breadth of the package of measures, but it would be useful for it to briefly set out the discounted options. However, generally the IAs should discuss alternatives to regulation for each of the proposals, and provide fuller assessment of the options considered.

## Cost-benefit analysis

The RPC considers the cost-benefit analysis to be satisfactory at this stage. The Adult Social Care IA now defines the baseline as local areas being legally obliged to assess patients in hospitals as they did pre-pandemic. The RPC is pleased to see that the Adult Social Care IA estimates the number of providers in the voluntary and community sector. However, the impact on CSOs should be better identified and analysed across all proposals in all three IAs.

## Wider impacts

The RPC considers the IAs’ assessments of wider impacts to be satisfactory at this stage. The Core Measures IA does not appear to consider wider impacts but does include a section on international trade. It states that in trade agreements the UK has and will always protect its right to choose how it delivers NHS health and care services.

The Additional Measures IA briefly discusses potential impacts on competition, innovation and trade. The Adult Social Care IA states that an equalities assessment has been carried out for all policy measures. The IAs could provide further detail on these wider impacts, the equalities assessment and the Department’s engagement with the Department for International Trade.

## Monitoring and evaluation plan

The RPC considers the monitoring and evaluation plan to be satisfactory at this stage. The Additional Measures IA suggests that a review will take place after 3 to 5 years and explains that the details of a PIR will be set out at secondary legislation stage. The IA would be improved if it provided some indication of the conditions under which carrying out a PIR might be deemed appropriate and more detail as to what would be considered. The Adult Social Care IA explains that there will not be any monitoring or evaluation of the provider payments legislation, but any individual payments will be reviewed on a case-by-case basis. It provides some detail on how the hospital discharge measure will be monitored. The IAs would benefit from clearly setting out which aspects of the proposals will be monitored, how they will be

monitored, and how the department will evaluate whether the policies have achieved their objectives.

### **Regulatory Policy Committee**

For further information, please contact [regulatoryenquiries@rpc.gov.uk](mailto:regulatoryenquiries@rpc.gov.uk). Follow us on Twitter [@RPC\\_Gov\\_UK](https://twitter.com/RPC_Gov_UK), [LinkedIn](#) or consult our website [www.gov.uk/rpc](http://www.gov.uk/rpc).

## Annex – List of proposals

### Core measures:

- Merging of NHSE and NHS Improvement
- Establish an integrated core system in law
- Joint comms and appointments
- Collaborative commissioning
- Triple aim
- Duty to cooperate
- Data sharing
- Foundation trusts capital funds limited
- Competition
- Provider selection
- National tariffs
- New Trusts
- Special Health authorities time limits
- Arms length body transfer of functions powers
- SofS intervention powers
- NHS Mandate
- Reconfiguration powers
- Public health power of direction
- Abolishing LETBs
- Workforce accountability

### Additional measures:

- Medicine registries
- Professional regulations
- Medical examiners
- Hospital food standards
- Water fluoridation
- Food info for consumers
- Reciprocal Healthcare for the rest of the world

### Adult social care provisions:

- Hospital discharge (D2A)
- Provider payments
- Enhanced assurance