Health and Care Act 2022

Lead department	Department of Health and Social Care
Summary of proposal	A number of measures were added to the Health and Care Bill during its parliamentary passage. These include measures relating to eradicating slavery and human trafficking in supply chains, the licensing of non-surgical cosmetic procedures as well as the banning of hymenoplasty and virginity testing.
Submission type	Enactment stage IA – 23 August 2022
Legislation type	Primary legislation
Implementation date	2022
Policy stage	Enactment
RPC reference	RPC-DHSC-5082(2)
Opinion type	Formal
Date of issue	5 October 2022

RPC opinion

Rating[1]	**RPC opinion**
Fit for purpose	The Department has provided a series of IAs covering the various and wide-ranging policies within the Act. The assessments of direct impacts on business of the policy measures added since the final stage IA are sufficient at this stage, but those assessments and the overall cost benefit analyses could be improved in several ways, as described below. *Note: the comments in this opinion are primarily confined to the assessment of measures added since the final stage IA. For the RPC's assessment of the IA for the Act as enacted, this opinion should be read in conjunction with the RPC opinion on the final stage IA.*

[1] 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.

Business impact target assessment

	Department assessment	RPC validated
Classification	Non-qualifying provision	To be determined at secondary legislation stages. This primary legislation has no impacts qualifying for inclusion in the BIT.
Equivalent annual net direct cost to business (EANDCB)	Unquantified	Further IAs to be submitted at secondary legislation stage for validation of EANDCB figures and contributions to the BIT, as appropriate.
Business impact target (BIT) score	N/A	See above.
Business net present value	Unquantified	
Overall net present value	Unquantified	

RPC summary

Note: The ratings for quality are as those in the final stage opinion, given that the additional measures form a minority of the overall policy package in the Act. However, the comments generally relate to the assessment of the measures added since the final stage IA.

Category	Quality	RPC comments
EANDCB	**Green**	No EANDCB figures are provided at this stage but the IAs provide a sufficient qualitative assessment of the impacts on businesses. The 'eradicating slavery' and 'licensing of non-surgical cosmetic procedures' IAs would benefit from providing an indication or illustration of the scale of net direct costs to business, where possible.
Small and micro business assessment (SaMBA)	**Green**	The IAs identify impacts on Small and Micro Businesses (SMBs). The IA on licensing non-surgical cosmetic procedures provides good information on the number of affected SMBs but would benefit from further discussion of the extent and potential mitigation of disproportionate impacts on SMBs.
Rationale and options	**Weak**	The Department has expanded its discussion of the intervention rationale for the provider selection and choice elements of the Core Measures IA. The new elements in the Additional Measures IA would benefit significantly from a stronger discussion of the problem being addressed and how the intervention will tackle it.
Cost-benefit analysis	**Satisfactory**	Overall, the IAs provide a sufficient analysis at this stage. There are areas to strengthen, particularly in relation to potential benefits in the IAs for measures regarding licensing of non-surgical cosmetic procedures and increasing gamete and embryo storage limits.
Wider impacts	**Satisfactory**	Overall, the IAs provide a sufficient assessment at this stage. As noted in the final stage opinion, the IAs would be improved by further details of how wider and indirect impacts, such as on competition and innovation, will be further assessed at secondary legislation stage.
Monitoring and evaluation plan	**Satisfactory**	The monitoring and evaluation plan is sufficient at this stage. As noted in the final stage opinion, the IAs would benefit from further details of plans, including how the Department will evaluate whether the measures have achieved their objectives.

Background and summary of proposal

This opinion provides an update to the 6 September 2021 RPC opinion issued on the final stage impact assessment (IA) for the Health and Care Bill.[2]. Given that the proposal has been enacted, the submission of this further IA for RPC scrutiny is primarily for business impact target accounting purposes - to ensure that the assessment of direct business impact fully reflects amendments to the Bill during parliamentary passage. The core of this opinion does not, therefore, cover impacts of any amendments that are not regulatory provisions under the SBEE Act 2015 and thus cannot qualify for scoring against the BIT, such as measures that regulate the public sector only (even where these might have business impacts). However, the 'other comments' at the end of this opinion includes comments or observations on some of these areas. For an RPC assessment of the IA for the Act as a whole and cross-impacts, this opinion should be read in conjunction with the RPC opinion on the final stage IA.

As noted in the previous opinion, the legislative changes were divided into three broad subsets: 'core measures'; 'additional measures'; and 'adult social care provisions'. The RPC is advised by the Department that there are no changes to the analysis of 'core measures' which affect businesses and that there are only minor changes to the assessment of the impact of 'adult social care provisions'. Nevertheless, there are some comments relating to changes in these IAs under 'other comments' at the end of this opinion. The Act does include six new 'additional measures' (these are listed as 8-13 in the analysis document covering additional measures):

i. Powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need for reimbursement under the standard NHS arrangements;
ii. Increasing gamete and embryo storage limits;
iii. Measures relating to commercial dealings in organs for transplantation: extra-territorial offences;
iv. Information about payments to persons in the healthcare sector, enforcement and consent;
v. Provisions to eradicate slavery and human trafficking in supply chains; and
vi. Licensing of non-surgical cosmetic procedures.

The Act also includes three further new measures with standalone IAs:

a) Virginity Testing Ban;
b) Health Services Safety Investigations Body (HSSIB); and
c) Ban on Hymenoplasty.

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1015756/2021-09-06_RPC-DHSC-5082_1__Health_and_Care_Bill_IA_RPC_opinion.pdf

On a), the RPC has already produced an opinion on the Virginity Testing Ban and there are no revisions to that IA.[3] On b), the Department reports that this measure is not a regulatory provision. The measure establishes a new independent, statutory non-departmental public body known as the Health Services Safety Investigations Body (HSSIB) to replace the Healthcare Safety Investigation Branch (HSIB), which has been in operation since 2017 as a branch of the Special Health Authority (now operating as NHS Improvement). On this basis, the RPC accepts that the measure does not regulate business and is not, therefore, subject to the requirements of the Better Regulation Framework. This opinion focusses, therefore, on the assessment of the six new 'additional measures' (i) to vi) above) and the separate IA on the measure banning hymenoplasty (c) above).

Additional measures

Measures v) and vi) appear to have the most significant impacts on business.

Eradicating slavery and human trafficking in supply chains.

The IA states that "*The regulations can apply to public bodies procuring goods or services for the health service…*" (page 52) and that "…*the information return is likely to require suppliers to undertake a supply chain mapping…*" (page 56). The IA would benefit from clarifying how the measure regulates businesses, in particular whether the regulatory requirements apply to public bodies only or also to their suppliers. This will be important to establish whether the business impacts would score for BIT purposes.

The IA provides a description of the costs involved and notes that these could be substantial (page 53). Although the IA explains why a detailed assessment is not provided at this stage and commits to doing so for the secondary legislation IA, the present IA would benefit significantly from an indication of the enforceability of the measures and the possible scale of costs, perhaps with reference to assessment undertaken for other measures requiring supply chain due diligence (including the Modern Slavery Act - Transparency in Supply Chains 2015). The IA would also benefit significantly from a stronger assessment and greater provision of evidence in relation to the problem being addressed, to support the case for going beyond the existing requirements on the NHS (listed at page 59) and of the likely benefits of the proposal. The IA notes that the measure could disproportionately affect small and micro-businesses (SMBs) but would benefit significantly from further discussion of this, the number of SMBs likely to be affected and potential mitigation.

Licensing of non-surgical cosmetic procedures

The IA discusses evidence of existing harm but would benefit from discussing the contribution of issues that the measure is intended to address, such as lack of training or poor hygiene. The IA would benefit from applying values for harm,

[3] RPC-DHSC-5021(1) Virginity Testing Ban, 19 November 2021.

perhaps informed by those used by DHSC in relation to quality-adjusted life-years (QALYs), to give an indication of overall potential benefits should the measure reduce harm. On costs, the IA usefully includes an annex that estimates the numbers of businesses and practitioners affected. The IA would benefit significantly from indicating the scale of overall impact, for example by using evidence on the typical cost of a licence - the IA presents figures from licensing schemes in Nottingham and Croydon (pages 68-69). The IA could also discuss any evidence of impact from these schemes. On SMBs, the measure clearly affects micro-businesses in particular because a high proportion of businesses are self-employed/sole traders. The IA provides a good presentation of the number and size of businesses affected in annex B, addresses why an exemption is not possible and briefly mentions potential mitigation through a transition period. However, given the disproportionate impact of the measure on SMBs, the IA would benefit significantly from further discussion of disproportionality and potential mitigation.

Other additional measures

On i) '*powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need to reimburse them under the standard NHS arrangements',* the IA would benefit from discussing further and, where possible, indicating the scale of the potential loss of profit to pharmaceutical warehousing businesses who could no longer purchase products from pharmaceutical wholesalers for resale to a purchasing service, but would instead merely supply a logistic service to sales from wholesalers to end customers.

On ii) '*increasing gamete and embryo storage limits'*, the additional measures IA refers to a separate published analysis for a full assessment of costs and benefits.[4] This analysis includes information on the number of businesses affected and a clear monetisation of one-off and recurring costs to these businesses. The analysis provides an assessment demonstrating that these costs to be low, which is proportionate at this stage. However, it focusses on costs and should also cover potential benefits to business, principally the potential additional profit to gametes and embryos storage businesses if individuals choose to pay for, longer storage of their gametes. Given that this would arise from a relaxation of an existing statutory storage limits, this could be considered to be a direct benefit to business.

On iv) '*Information about payments to persons in the healthcare sector, enforcement and consent'*, the present IA would benefit from including summary information from the consultation stage IA for the secondary legislation, which provides an initial estimate of direct ongoing administrative costs to in-scope businesses.

Ban on Hymenoplasty

[4] https://www.gov.uk/government/consultations/egg-sperm-and-embryo-storage-limits/outcome/regulatory-triage-assessment-for-increasing-gamete-and-embryo-storage-limits-to-a-maximum-of-55-years-for-all

The IA clearly identifies the issue being addressed, notes the limitations of available data and assesses impacts on SMBs. As with the virginity testing ban IA, this IA usefully seeks to 'sense-check' its cost estimates using other data and, being unable to monetise benefits, conducts a break-even analysis. The Department's analysis is sufficient to demonstrate that direct business impacts are likely to be very small and within the *de minimis* threshold if this were a standalone measure (paragraph 88, pages 19-20). However, there are two significant areas for improvement:

- The IA monetises lost profits to private clinics; these should be included in the EANDCB. Even if the clinics reduce these losses by providing other services (paragraph 89, page 20), that would be an *indirect* impact of the measure.
- Although not included in the EANDCB figure, the IA refers to the benefit to civil society organisations (CSO) of being able to move resources previously devoted to campaigning against hymenoplasty to alternative uses as a direct benefit to business/CSOs (paragraph 135, third bullet). Any impact resulting from such a reallocation would, however, be indirect.

The Department may wish to refer to RPC guidance on these types of issues.[5]

Other comments

Core measures IA

The IA includes the following measures that were not covered in the final stage IA:

- 6. Care Quality Commission reviews of Integrated Care Systems (page 25)
- 16b. NHS England mandate: cancer outcome targets (page 50)
- 21. Designating Integrated Care Boards as Operators of Essential Services under NIS Regulation (21-26 covered at pages 58-75)
- 22. Information about inequalities
- 23. Further embedding research in the NHS
- 24. ICB and NHSE inequalities duty extension
- 25. Climate change duties
- 26. Accountability and Transparency of Mental Health Spending.

None of these measures appear to regulate business, although CQC ICS reviews (the first item above) could ultimately involve familiarisation and possibly on-going costs for "organisations in the system" (which would presumably including private sector social care providers) that will have to comply with any inspection requirements. The IA provides a satisfactory description of these costs at this stage and explains that it is not currently possible to go further as the CQC has not yet determined or tested the methodology for ICS reviews. The RPC would welcome the opportunity to discuss further with the Department such business impacts in relation to any secondary legislation.

[5] https://www.gov.uk/government/publications/rpc-case-histories-direct-and-indirect-impacts-march-2019

There are significant additions to the text in relation to the following measures since final stage: '7. Data Sharing' (pages 27-33) and '10. Provider Selection and Choice' (pages 37-43). On Data Sharing, the Department has usefully substantially expanded its discussion of potential costs, including on business (pages 29-32). On Provider Selection and Choice, the IA includes more discussion of rationale and has substantially expanded its discussion of potential costs, including scenario analysis (pages 38-41).

Adult Social Care Provisions - Hospital Discharge IA

The IA states that option 3 (remove current legislative barriers to assessing post-discharge) is "preferred" but includes costs and benefits for an alternative option (option 2 – legislate to require assessment post-discharge and ensuring that carers and patients are involved in discharge planning). Given that this is an enactment IA, the IA would benefit from providing greater clarity around the policy to be implemented. For example, one of the most substantial additions to the IA, at pages 40-43, covers "*additional costs and benefits identified in response to the government amendment introduced in the final stages of the Bill process to include carers in discharge planning*". A cost estimate for this is included in the costs of option 2 (Table 1, page 44) but not the preferred option 3.

The IA would be improved by further assessment of:

- the full costs of post-discharge assessment in terms of shifting costs to outside responsible parties, regardless of their ability to bear them (some of these will fall on businesses as well as local authorities);
- costs of post-discharge adjustments to locations and care provision (e.g., if people are discharged into unsuitable environments; and
- additional costs arising from delayed or inappropriate assessments (e.g., when NHS assessments would give different results than whomever does it under option 3.

The illustrative estimates of costs and benefits for option 3 (the preferred option) have fallen markedly from the final stage IA, with the cost of 'provision of recovery services' reducing from £7.8bn to £5.4bn; 'coordination costs' from £1.3bn to £0.8bn; and benefit to 'care receivers' of 'Less long-term care provision from £7.9bn to £5.5bn. The IA would benefit from explaining the evidence and analysis behind these changes, making it clear, now that the figures are presented in the summary sheets, that they are illustrative only and providing evidence that they are realistic in light of current conditions. The IA should also provide analysis and evidence to show that it has taken into account recent relative price rises in the health and social care sectors.

HSSIB IA

As noted above, the HSSIB measure is not a regulatory provision, so the RPC has not scrutinised its IA. However, the RPC notes that the Department has applied a multiple of four to the estimated running cost of the new HSSIB, reflecting the that a quality adjusted life year (QALY) is worth £60,000 to society, while the NHS spends £15,000 to achieve it - page 3 and paragraph 77, page 15 of the IA. Whilst it is

reasonable for the Department to use such a multiplier to optimise its spending within a budget constraint, it is the RPC's understanding that this is not an appropriate measure of the opportunity cost of exchequer funding and should not be used in regulatory impact assessments. This is covered in RPC guidance.[6] The IA would also benefit significantly from including a monitoring and evaluation plan.

Regulatory Policy Committee

For further information, please contact regulatoryenquiries@rpc.gov.uk. Follow us on Twitter @RPC_Gov_UK, LinkedIn or consult our website www.gov.uk/rpc.

[6] https://www.gov.uk/government/publications/rpc-case-histories-december-2016-volume. pp 70-71.