The Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) [No. 2] Regulations 2021 - COVID-19 Vaccination as a Condition of Deployment in Health and Care providers

Lead department	Department of Health and Social Care
Summary of proposal	Making COVID-19 vaccination a condition of deployment in health and adult social care settings (domiciliary care and other Care Quality Commission (CQC) regulated settings).
Submission type	Impact assessment (IA) – 15 November 2021
Legislation type	Secondary legislation
Implementation date	1 April 2022
Policy stage	Final
RPC reference	RPC-DHSC-5132(1)
Opinion type	Formal
Date of issue	29 November 2021

The Regulatory Policy Committee is the Better Regulation watchdog. We are an independent body, sponsored by the Department for Business, Energy and Industrial Strategy (BEIS), with a formal role to scrutinise impact assessments (IAs) for most significant new regulations proposed by the Government where there are direct costs on business greater than +/- £5m. The Committee is formed of independent experts from a range of backgrounds, including the private and voluntary sectors, business, the legal profession, and academia. Collectively, the RPC has experience and knowledge of business, employee, consumer and economic issues.

We have a role to fulfil in validating the assessments of EANDCB and we “red rate” IAs on both this aspect and on their consideration of small and micro business impacts. Beyond that, we offer our opinion on the Department's IA based on our comparison of the levels of evidence provided in other IAs that we considered fit for purpose. The RPC does not comment on Government policy objectives and nothing in this opinion should be interpreted as a verdict on the Department's policy choices or recommendations for public health measures.

RPC opinion

Rating[1]	RPC opinion
Not fit for purpose	The Department's IA does not provide the level of economic evidence for the calculation of direct impacts and the consideration of the impacts on small and micro businesses which are usually included in IAs deemed fit for purpose. The IA does not provide evidence that excluding unvaccinated staff from health and care services will not result in critical staffing shortfalls, or sufficient evidence that such shortfalls could be avoided. The IA would have been improved with evidence from the staff consultation as to the motivations of those who had chosen not to be vaccinated, to understand different options for achieving the public health objectives We have concerns about gaps in the economic evidence, as well as cost estimates and potential mitigations for small and micro size business, as discussed below. We note that vaccine mandates have been implemented abroad, and the IA would have been strengthened by evidence concerning the impacts of such policies.

Business impact target assessment

	Department assessment	RPC validated
Classification	Qualifying regulatory provision	Qualifying regulatory provision
Equivalent annual net direct cost to business (EANDCB)	£94.9 million	Unable to validate
Business impact target (BIT) score	£94.9 million	
Business net present value	-£94.9 million	
Overall net present value	-£251.2 million	

[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 rates IAs as either 'fit for purpose' or 'not fit for purpose'.

RPC summary

Category	Quality*	RPC comments
EANDCB	**Red**	The IA describes the main costs as the recruitment costs to replace workers that do not fulfil the vaccination condition. The analysis monetises these costs by estimating the proportion of the workforce affected (across different sectors) and applies simplified recruitment cost assumptions. The analysis assumes that the unit costs applied are a suitable proxy for all health and social care providers. Given the centrality of these unit cost assumptions to the policy impacts, both the number of workers affected and the costs per worker need to be corroborated better by evidence and subjected to further sensitivity and scenario analysis. The IA must also seek to include, where possible, all the direct costs falling on independent (private) providers.
Small and micro business assessment (SaMBA)	**Red**	The IA states that the majority of independent organisations that operate as health and social care providers are small and micro businesses (SMBs) or civil society organisations (CSOs), setting out the share of businesses by size across the health and care sectors. The IA highlights the disproportionate impact on SMBs. However, there is limited discussion of the impact of intensified staff shortages and the potential difficulties in recruitment, which will be critical for SMBs. Although the IA explains why SMBs are not exempt and presents some general mitigating factors, such as the provision of guidance and support, these do not clearly address the issues facing SMBs and are not designed specifically for these businesses.
Rationale and options	**Satisfactory**	The IA sets out the problem under consideration sufficiently, highlighting the vulnerability of many patients and the variation in vaccine uptake across health and care settings. The IA establishes a valid baseline for vaccination take up, supported by appropriate evidence. Alternative options to achieve the policy objectives have not been explored.
Cost-benefit analysis	**Weak**	While the analytical approach is appropriate, the limited evidence used to inform the analysis on the behaviour of private providers (businesses) to meet the conditions and maintain health and social care

		delivery appears insufficient. The analysis should reflect the significant risks and uncertainty in the evidence and key assumptions used. The IA should also consider the costs to public sector and the costs to the CQC, as the enforcement body.
Wider impacts	**Weak**	Although the IA briefly considers several wider impacts, the IA should provide more detail on the potential competition impacts, especially on the independent (private) sectors affected. The IA usefully provides analysis on protected characteristic groups, highlighting those most likely to be unvaccinated, or vaccine hesitant.
Monitoring and evaluation plan	**Weak**	The IA sets out the Department's intention to engage with the relevant sectors to assess the impact of the regulations. The IA mentions how the CQC will monitor compliance, which could be discussed in more detail. The Department should consider how it will use monitoring and evaluation (M&E) to fill any evidence gaps on the risks and uncertainty, and long-term effects, including any unintended consequences.

Summary of proposal

The regulations will place requirements to be vaccinated on all health and adult social care staff and volunteers who have face-to-face contact with patients and who are directly involved in patient care, as well as ancillary staff such as porters or receptionists who may have social contact with patients but are not directly involved in their care. This requirement will apply to all those deployed to undertake CQC-regulated activity in either the public (NHS) or independent health, domiciliary care, and other adult social care settings.

The IA describes the main monetised costs of this policy as the recruitment costs to health and adult social care providers of replacing workers who have not fulfilled the requirement of having both doses of the vaccine by the end of a 12-week grace period. The Department has estimated the policy to have a social net present value of £-251.2 million and an EANDCB of £94.9 million. Both figures are assessed over a one-year appraisal period only.

The IA also sets out several additional costs that have not been monetised, which could add to the financial and non-financial pressures faced by providers, potentially leading to lower quality and/or gaps in care which are:

- **potential disruption** to health and care services from the need to replace unvaccinated workers;
- **productivity losses** if new, relatively inexperienced staff are recruited to replace staff who leave;
- **productivity losses** from staff absences arising from side effects and potentially lower morale of staff if they feel forced into having vaccination (and if they have to cover staff shortages at a time of already overwhelming pressure);
- **familiarisation costs** to the health and care providers to become aware of the regulation and its guidelines;
- **administrative costs** to health and care providers who must deal with complications arising from the regulation, including the redeployment of workers; and
- **costs of vaccinations** (excluding the sunk costs of vaccine purchases, but including the personnel and administrative costs of delivering them).

The IA describes the main monetised benefits of the policy as:

- direct health benefits to individual health and care workers;
- the associated avoided sick leave for these workers;
- the reduction in hospitalisation costs resulting from averted COVID-19 infections; and
- unmonetised benefits including general health benefits of the expected lower rates of COVID-19 infection, and wider societal benefits (in health, wellbeing and economic) resulting from a higher vaccination rate and a greater level of reassurance provided to patients and care users.

EANDCB

To calculate recruitment costs, the IA uses a simplified assumption that replacement staff are available immediately from the wider labour market. It uses very general proxies for the staff covered by the measure: specifically, for health providers, the recruitment costs faced by the NHS for the administration, interview process and induction of a Band 5 nurse (£2,100) (as representative of typical NHS workforce); and for social care settings, a unit cost of £2,478, per worker, derived from the stated costs of recruitment by one small adult social care provider.

Of the several additional costs not monetised, the direct costs to business include familiarisation costs to health and care providers, and the costs to health and care providers of covering staff absences due to side effects from having the vaccination.

The IA highlights significant uncertainties around the change in the willingness of staff to be vaccinated as a result of these regulations, and the extent and timing of workers' decisions to leave their jobs. Where possible and available, the analysis should draw on the international evidence base, which could help inform workforce estimates.

Red-rated issues

- **Unsupported assumptions –** The unit cost assumptions are overly simplistic, given the diverse number of sectors, businesses and staff affected by the measure. Further justification is needed that these simplified unit costs are reasonable estimates of the average costs across the diverse sectors, or an explanation of why their use is proportionate. Further scenario and sensitivity analysis needs to be included, to illustrate how sensitive the overall costs are to these assumptions. In addition, the evidence on the number of workers who would need to be replaced should be supported by a better evidence base – preferably using evidence from similar measures internationally.
- **Unmonetised costs –** It is unclear why some of the direct costs (such as familiarisation and staff absences) are excluded from the final EANDCB figure. The IA must seek to identify all direct impacts of the regulations or demonstrate that it would not be possible or proportionate to include these direct costs within the EANDCB figure.
- **Suitability of the evidence base –** The IA needs to discuss further the robustness and applicability of NHS and social care data, to independent healthcare providers, primary care services (e.g., private GP practices and dental practices), and other health and social care providers, and must supplement these estimates and assumptions with corroborating evidence from different sectors and stakeholders.

SaMBA

The Department has identified that most entities that operate as health and social care providers are SMBs or CSOs, providing a breakdown of the sector by business size across the individual business categories within these sectors. The IA highlights that SMBs may face disproportionate costs as a result of the policy. The IA states clearly that an exemption

for SMBs would not be suitable, because the high proportion of SMBs in the affected sectors would limit the attainment of policy objectives.

The IA points towards guidance that will be published to assist healthcare providers with the implementation of, and compliance with, the regulations. For social care providers, the IA notes that, in addition to guidance on implementation, best-practice guidance will also be made available to support SMBs in the sector. The RPC also welcomes the Department's commitment to working with local authorities.

Red-rated issues

- **Full consideration of SMB impacts –** The IA must consider if the current challenges that SMBs face in comparison to larger health and social care employers, including recruitment and retention, may be exacerbated by this measure. The IA has not considered cases where an unvaccinated person is a sole trader, self-employed or the key provider of patient services in a business and therefore, any restriction on their deployment prevents the business from operating within health and social care settings.
- **Voluntary sector impacts –** The Department must consider how the policy will affect CSOs and their volunteer staff who may have contact with patients.
- **Appropriate consideration of mitigation –** The IA does not include appropriate consideration of mitigation alternatives for SMBs, such as regular testing, (particularly for workers who may have some, but not frequent contact with patients). The IA must provide further details of consideration of mitigations, or justification of why potential mitigation would not be appropriate.

Rationale and options

Rationale

The IA provides a clear rationale for regulatory intervention, citing the need to ensure those entering these workplaces, and interacting with patients in a face-to-face setting, protect those most vulnerable. The IA highlights that the current national vaccination programme, encouraging those unvaccinated to receive the vaccine, will continue to operate alongside these regulations.

The IA would benefit from discussing in the rationale the increasing risk from waning immunity over time for people who have not had 3rd (booster) vaccinations and how this is likely to affect the achievement of this measure's objectives, especially given that health workers will have been among the first to have been vaccinated.

The Department includes findings from a recent consultation, which is welcomed, and which shows that stakeholders who responded were not in favour of extending the requirement to be vaccinated prior to deployment to more employment settings. Given the findings of the consultation the IA should consider explaining why the proposed extension of the policy is appropriate.

Options

While the option that has been considered is sufficient in addressing the policy objective of increasing the vaccination rate in health and social care sectors, the IA could consider alternative options to help protect those who use health and social care services, as well as the staff themselves. For example, the IA could discuss requiring regular negative lateral flow tests (as required in schools and as has been adopted in other countries), as an alternative to vaccination and as a check on the risks posed by waning vaccination immunity.

Cost-benefit analysis

Counterfactual/baseline

The IA establishes a valid baseline, using the latest available data on vaccination take-up rates amongst NHS staff and domiciliary and other social care settings. In the health sector, 1.813 million staff will be subject to the new regulations across both the NHS and independent health care providers. Of these, 1.679 million are already vaccinated and establishes the baseline. Similarly for domiciliary and other social care settings, 503,000 staff will be subject to the new regulations of which 428,000 are already vaccinated.

Methodology

The analytical approach for the cost benefit analysis appears to be suitable, estimating the size of the workforce on which the regulations will have an impact and identifying the subset of workers that may no longer qualify to work in the sector due to the vaccination condition being proposed and then multiplying this number by a unit cost per worker based on the expected recruitment costs.

The IA presents estimates of NHS and social care workforce figures but, while presentational, there appears to be inconsistencies in the estimates and rounding which could, when used in the analysis, be compounded and affect the accuracy of the EANDCB figure.

The analysis presents low and high scenarios for workforce estimates and the central estimates are used to calculate the costs of the impacts. However, the ranges are very wide and the central or mid-point estimates need to be supported by further corroborating evidence to ensure that they are a reasonable estimate of the expected costs.

As a proxy for all staff within health providers, the recruitment costs reflect those faced by the NHS for the administration, interview process and induction of a Band 5 nurse (£2100) as a representative of typical NHS recruitment costs. For social care, the IA uses a unit cost of £2478 per worker derived from the stated costs of recruitment by a small adult social care provider. These unit cost assumptions appear too simplistic and unsupported given the diverse number of sectors, businesses and staff affected by the measure. Further justification is needed that these simplified unit costs are reasonable estimates of the average costs involved.

Other indirect impacts
While the IA considers the impact of needing to replace those workers who choose not to be vaccinated, it does not consider the potential knock-on effects and costs of replacing workers who leave as a result of feeling under pressure due to increased resourcing constraints, redeployment or who feel unfairly treated compared to workers not subject to these requirements. Although these impacts would be treated as indirect, the IA would be improved by their consideration.

The potential disruption as a consequence of the regulations may well go beyond the recruitment costs of replacing unvaccinated workers; both public and private providers may need to:

- pay increased costs (staff overheads) due to higher and longer-held vacancy rates; offer premiums for existing employees to cover staff gaps;
- compensate for any adverse impacts on retention of existing employees;
- offer higher wages to attract new workers from a contracted labour market pool; and/or
- incur higher costs to bring in locums or temporary staff.

These workforce costs are likely to affect private sector service delivery (output) adversely, and the loss of service output due to labour market contractions resulting from the vaccination condition will affect independent providers' revenues and profits.

Public sector
The IA explains that the CQC will have the role of monitoring and taking enforcement action at the time of registration or when providers are inspected. The registered person/organisation would have to provide evidence that those deployed to undertake the regulated activity have been vaccinated. The IA should include a discussion of the scale of the additional costs to the CQC resulting from these new requirements.

Wider impacts

Competition
The IA includes a brief section covering the competition impacts of the policy. While this addresses the potential for firms which have higher rates of vaccination seeing an increase in business, the Department should explore the competition impacts further. In particular, whether there will be an impact on the ability of small and micro businesses to be able to attract and compete for workers, if the policy were to result in increased rate of workforce churn. Furthermore, the IA should consider the impact on competition between providers due to factors such as characteristics of the populations they serve or characteristics which form part of the workforce, geography, and other socio-economic conditions.

Distributional
The IA usefully highlights the impact on protected characteristics and rural areas. The IA should consider further the existing challenges facing rural health and social care provision and whether this may result in a disproportionate impact on these communities.

Monitoring and evaluation plan

The IA sets out the Department's intention to engage with the health, social care and other health setting sectors to assess the impact of the policy. It also proposes using existing data collection to monitor impact across workforce vaccination rates (including by region), staff number levels as well as absence and vacancy rates.

The IA also proposes that the CQC will monitor and enforce compliance with the regulations. As part of the wider M&E plan, the IA would benefit from discussion of how this would be done, and how it will align with the CQC's existing powers.

The Department should include a discussion of how, through further review, it would examine and test the risk, uncertainty and assumptions (in particular those relating to the unit costs of workforce replacement).

Other comments

We note that these regulations apply to England only. While the IA highlights that the devolved administrations (DAs) are being kept informed of the development of this policy, the IA would benefit from a discussion on whether similar policies are being considered in DAs and what impact may occur in communities or for healthcare providers near the respective borders if the policies are not aligned.

Regulatory Policy Committee

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