Regulatory Policy Committee	**Opinion**	
Impact Assessment (IA)	Fit and proper persons requirements for Directors	
Lead Department/Agency	Department of Health	
Stage	Consultation	
IA Number	6111	
Origin	Domestic	
Expected date of implementation (and SNR number)	-	
Date submitted to RPC	06/01/2014	
RPC Opinion date and reference	14/02/2014	RPC13-DH-1991
Overall Assessment	**AMBER**	

RPC comments

The IA is fit for purpose. To assist the consultation the IA should be strengthened, particularly in relation to the rationale for intervention, options considered and the impact of the proposal on small and micro businesses.

The final stage IA should ensure that the points below have been addressed prior to submission to the RPC.

Background (extracts from IA)

What is the problem under consideration? Why is government intervention necessary?

Directors of health and social care organisations play a crucial role in determining the safety and quality of care provided by the organisation through the decisions that they make and the culture that they set for the organisation as a whole. However, there are currently no requirements to ensure that directors of these organisations are, and continue to be, fit and able to carry out their role. It is at the discretion of the provider to ensure that the directors they appoint are of the right character and possess the necessary skills to carry out the role and to remove those who are not. In some cases this does not occur. Government intervention is required to close this gap in regulations.

What are the policy objectives and the intended effects?

The policy objective is to ensure providers take proper steps to ensure that their directors are fit and proper for their role. Requirements will be placed on providers to undertake the necessary checks to ensure that all directors exhibit the correct types of personal behaviour, technical competence and business practices required for their role. This is expected to have a positive impact on the quality of care by reducing the risk of there being unfit directors in post who negatively impact on the safety and quality of care. This will also strengthen the performance of directors by increasing the incentives on providers to scrutinise their performance and will enable CQC to take action against unfit directors including barring them from individual posts.

Identification of costs and benefits, and the impacts on business, civil society organisations, the public sector and individuals, and reflection of these in the choice of options

The IA assumes that 20% of providers are not currently undertaking proper reviews of the fitness of their directors. Using this, the Department estimates that approximately 2,070 providers will be most affected by the proposal. About 90% of these are in the private or voluntary sector. The majority of the costs are accounted for by staff costs in relation to ongoing monitoring and inspection. Overall, direct costs to business are estimated at -£10.0 million NPV over 10 years (with an EANCB of £0.94 million). Costs falling on the Care Quality Commission (CQC) account for most of the remaining cost in the total NPV of -£18.6 million.

Rationale for Intervention. The IA provides some rationale for intervention (paragraphs 11-12), with reference, for example, to the asymmetry of information between service providers and users. However, the rationale for intervention should be strengthened. In particular, empirical evidence should be presented of there being a problem.

Options. The IA presents some discussion on alternatives to regulation and other possible options (paragraphs 33-36). This includes an explanation for why voluntary codes of conduct would not provide sufficient incentives to change behaviour. However, this section should be strengthened. This applies, in particular, to the analysis of why alternative options are not being taken forward.
Definitions. The IA seeks to set out the requirements that providers will need to undertake to ensure that their directors are 'fit and proper' (paragraph 21). However, the IA should define more clearly what constitutes "fit and proper", thereby providing for greater clarity on what checks would be required.

Number of providers affected. There are two areas where further justification of the number of providers affected should be provided:

i) Stock of providers. The IA appears to deduct newly registered providers from the stock of existing providers (paragraph 40). It is not clear why the estimated impact on existing providers should exclude these;

ii) Flow of (new) providers. It is not clear why the number of providers is assumed to be flat over the next ten years, when it would appear to be likely that this will be a growing sector.

Costs. The Department explains that, due to lack of data and difficulty in making assumptions, a number of these monetised costs are illustrative at this stage. We note the Department's intention to strengthen the estimates for final stage. In particular, the assumption of 20% of providers not currently undertaking proper reviews of the fitness of their directors should be tested (paragraph 42).

There are also some areas where further clarification would help:

- more explanation of how the number of care homes affected in the private and voluntary sector is calculated (paragraphs 40-41);

- explanation of the cost estimates, especially the basis for arriving at the proportion falling on the private sector (paragraphs 53-56);

- including in the summary table references to the paragraphs where the figures have been calculated (paragraph 102).

Benefits. There are two areas in particular where the IA could provide further explanation:

i) the assumption that there will be a saving of 1/12 of a Quality Adjusted Life Year (QALY) per care home affected;

ii) how far the problems experienced, e.g. at Mid-Staffordshire Hospital and Winterbourne View Hospital, could be attributed to poor governance and therefore potentially prevented or reduced by these proposals.

Risks. The IA refers to the possibility of the fit and proper requirement deterring people from volunteering as directors for charitable organisations (paragraph 85). The consultation period should be used to assess how significant this might be.

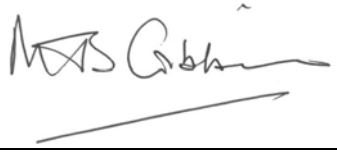
Cross referencing. The IA is part of the Government's commitment to ensuring that users of health and social care receive high quality and safe services. The IA would benefit from cross referencing to the other IAs within the commitment (entitled Duty of Candour and CQC – Fundamental Standards) to inform the consultation, explaining why this further piece of regulation is also thought to be required.

Comments on the robustness of the Small & Micro Business Assessment (SaMBA)

The IA provides a SaMBA (paragraphs 125 -126). This states that costs to small providers would be minimised by the CQC's proportionate and risk-based regulatory approach. The SaMBA should be strengthened significantly, giving more explanation about how the burdens on smaller firms would be mitigated. It should also provide information on the number of small and micro-businesses affected.

Comments on the robustness of the OITO assessment.

The IA says that this is a regulatory proposal that is in scope of OITO and would impose a direct net cost on business (an 'IN'). Based on the evidence presented this assessment appears reasonable and is consistent with the current Better Regulation Framework Manual (paragraph 1.9.10). The evidence supporting the estimated Equivalent Annual Net Cost to Business will have to be strengthened so that it can be validated at final stage.

Signed  **Michael Gibbons,** Chairman