 Regulatory Policy Committee	Opinion	
Impact Assessment (IA)	Duty of Candour on Providers	
Lead Department/Agency	Department of Health	
Stage	Consultation	
IA Number	-	
Origin	Domestic	
Expected date of implementation (and SNR number)	-	
Date submitted to RPC	11/10/2013	
RPC Opinion date and reference	21/11/2013	RPC13-DH-1928
Overall Assessment	AMBER	
<p>RPC comments</p> <p>The IA is fit for purpose. The IA should be strengthened, in relation to the points below, in order to assist the consultation. The final stage IA should ensure that these points have been addressed prior to submission to the RPC.</p>		
<p>Background (extracts from IA)</p> <p>What is the problem under consideration? Why is government intervention necessary?</p> <p>Although it is widely recognised that providers of health and social care should inform and apologise to service users where something has gone wrong in their care, there are many barriers that prevent this from occurring. The existing framework of policies, initiatives and levers designed to encourage candidness is currently not sufficient to overcome these barriers. Current requirements remain fragmented and vary in their effectiveness. Some providers face only weak or no requirements to be candid and there is scope for improvement even where existing levers are strongest. Government intervention is required to create a consistent standard across all providers.</p> <p>What are the policy objectives and the intended effects?</p> <p>The policy objective is to place a requirement on all providers of health and social care to ensure that they are open and honest with service users where there has been an incidence of serious injury or death. Providers will be expected to encourage and support staff to have open and honest conversations and to create a culture of openness and transparency within the organisation. The intended effect is to reduce the level of upset, anger and frustration that service users experience when they do not get all the information to which they are entitled and to improve reporting and learning from incidences by providers.</p>		
<p>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</p> <p>The proposal aims to introduce a statutory duty of candour on health and social care providers, and explains how this would impact on businesses by way of setting up and running the necessary and appropriate systems to meet the requirements of the proposal. By far the largest cost (£80.2m out of £87.5m NPV) relates to training and support staff in health and social care providers, of which just under half is currently estimated to fall on business.</p>		

Impacts on Business. The IA says that “we consider NHS Trusts, GPs and dentists as public sector organisations”(paragraph 34). The IA does not appear to include private sector GP and dental practices in the assessment of impacts on business. The Department should use the consultation to assess the inclusion of these practices within the scope of the impact on business.

Costs and Benefits. The IA provides a summary of the costs of the proposals (table at paragraph 82). The IA would benefit from an explanation on the aggregate cost estimates (paragraphs 49-53), particularly as these appear to relate to the largest cost category (training and supporting staff in health and social care providers) in the table at paragraph 82.

The IA indicates that the expected impact on clinician/manager time will be minimal (paragraph 55) but the evidence for this seems limited. The consultation should seek more information on this and also on whether there would be an impact on insurance costs (paragraph 72).

We note that the IA has begun to develop quantification of benefits (paragraphs 86-88). The final stage IA should develop this more fully.

Options. The IA presents costs and benefits in relation to only one option: to introduce a statutory duty of candour in the Care Quality Commission’s (CQC) registration requirements. The IA does provide some limited discussion of the possibility of alternative options (paragraphs 30-32) and refers to an earlier consultation. However, to assist this consultation, the IA should provide more detail on possible alternative options and say how these were considered. The final IA should also include significantly more detail on why non-regulatory options were rejected.

Business NPV and Summary Sheet. In separating out the costs to business (table at paragraph 92) the IA discounts the costs back to 2010/11 to arrive at the Business NPV figure. However, while this is the correct procedure to calculate the EANCB (although this should be to 2010 rather than 2010/11) it should be noted that the Business NPV should be presented in the same base year (and price base) as the overall NPV. At present the NPV and Business NPV on the front page of the IA are not directly comparable. This should be amended in the final stage IA.

Sensitivity Testing. We note that the IA (paragraph 94) applies sensitivity testing to a series of scenarios resulting from varying assumptions within the IA. The final stage IA would benefit from the inclusion of further detail on the calculations involved in arriving at the revised NPVs and EANCBs.

Cross reference with IA on CQC Requirements. The IA discusses the suite of enforcement actions open to the CQC if a provider is found in breach of the duty of candour (paragraph 29). In particular, these include the use of warning notices prior to seeking a prosecution. However, an associated IA proposes to remove warning notices in order to improve the effectiveness of CQC’s enforcement role. The Department should address this point by clarifying the inclusion of the warning notices and make clear cross reference to the associated IA covering the proposal to remove these notices.

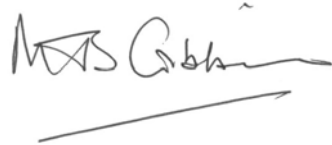
Comments on the robustness of the Small & Micro Business Assessment (SaMBA)

The IA provides a SaMBA at paragraphs 104-105. This appears to justify why small and micro-businesses should not be exempt and explains briefly how impacts might be mitigated. The final stage IA should provide information on numbers of small and micro-businesses affected, take into account the comments under '*Impacts on Business*' above and include more detail on how impacts will be mitigated.

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 to 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

A handwritten signature in black ink, appearing to read "Michael Gibbons", with a long horizontal line underneath it.

Michael Gibbons, Chairman