

## Annex B - Fundamental standards consultation responses by question

### **1 Do the Fundamental Standards regulations make clear the kinds of outcomes we expect providers to meet/avoid?**

The majority of responses to this question agreed that the regulations made clear the kinds of outcomes we expect providers to meet or avoid. A proportion of these felt that although they were generally clear, there were still some ambiguous phrases.

Many respondents explained that they thought our drafts were easier to understand than the present regulations, clear, relevant and sensibly structured.

Some respondents took the opportunity to ask more detailed questions, suggest specific changes, or outline more general issues not related to the question.

Common themes from the comments were that there are some ambiguous words, that the simplified regulations would need to be accompanied by credible guidance, and that clear regulations only work if they are consistently applied by CQC inspectors.

### **2 Do you think the Fundamental Standards regulations reflect the policy aims we have set out for the Fundamental Standards?**

Generally the response was positive, with many people expressing enthusiasm for the fundamental standards overall.

Some respondents provided detailed comments explaining where they thought the policy aims were met and were not met. Issues were raised with the ambiguity of particular words or phrases.

Some respondents reserved judgement, for example because they thought the regulations were still subject to interpretation, guidance, and consistent application, and ultimately all of these factors would contribute to determining whether the aims are met.

### **3 Do you think any changes are needed to the draft regulations to ensure they reflect the policy aims we have set out?**

Although a sizeable minority did not feel any changes were needed, a majority thought that changes were needed to the regulations.

A wide range of comments were received in response to this question ranging from suggestions for minor changes, to more fundamental issues about the way the regulations worked. The comments and suggestions received led us to make many

changes to the draft regulations. We have summarised the issues raised and our responses elsewhere in this document.

#### **4 Do you agree that the health and adult social care system should always seek to meet the standards?**

The majority of respondents agreed that the health and adult social care providers should always seek to meet the standards, with many pointing out that they set out a basic level of quality and safety that all providers should be able to achieve. For many, system-wide adoption of the standards was seen as essential, and would provide important reassurance for people receiving care. Some respondents commented that the standards may not always be applicable in the same way in all settings.

#### **5 Are the Fundamental Standards (regulations 4-14) clear enough that they could be used as a basis for enforcement action?**

A majority of the responses considered that the standards were clear enough to be a basis for enforcement action.

Some respondents were very satisfied that they could be used as a basis for enforcement action without the need for changes. Many others agreed this was the case, while still accepting they contained ambiguity. People again took the opportunity to bring up issues about ambiguous terms, or requests for clearer meanings.

Those who thought they were not clear enough pointed out that as drafted they were open to interpretation in many places, subject to explanation in guidance, and dependent on consistency of application by inspectors. There was some concern that unless the ambiguity was removed, the potential for subjective interpretation and inconsistent enforcement action remained. As noted elsewhere, we have tried to remove as much ambiguity as possible.

Some responses reflected that it will always be difficult to achieve 100% consensus between regulator and providers about enforcement. Some responses spelled out detailed hypothetical scenarios to illustrate this.

Generally, most respondents thought that the publication of appropriate guidance and enforcement policy from CQC should help to provide more certainty, for example by defining ambiguous terms and setting out how the standards apply in a particular setting or circumstance.

#### **6 Regulation 17 sets out which of the regulations are offences for which CQC will still need to issue a pre-prosecution notice for, alongside those that could be prosecuted immediately. Do you think this split reflects our intention (see**

**chapter 4) that only breaches related to a harmful outcome can be prosecuted without a pre-prosecution notice being issued in advance?**

Most respondents thought the split was a good thing, and the emphasis on harm was the right one, and they understood the principle.

Some people found the regulation itself confusing and found it took time to fully comprehend as originally drafted.

Some questioned whether standards like dignity and respect and person-centred care would ever be clear enough to support a prosecution, given their inherent subjectivity. Several questioned whether having a complaints process should be prosecutable.

Others questioned whether the split introduced a hierarchy, and asked whether that was really the intention, especially since it sent a message that breaches of some standards were less serious. The main point of contention people highlighted was with staffing – the suggestion being that low staff numbers can relate directly to harm.

Others raised practical points about how the existence of a warning notice for some offences but not others would affect potential enforcement action where a prosecution related to both types of breach, for example a breach of the safe care regulation, and a breach of the staffing regulation.

**7 Do you agree that CQC's guidance about complying with these regulations should set out criteria for cases in which it would consider bringing a prosecution?**

There was very strong support for CQC guidance setting out the criteria for cases in which it would consider bringing a prosecution.

Almost all respondents who commented agreed that the CQC guidance will need to be very clear about how providers are expected to comply with regulations, and what CQC's enforcement action may look like. Points were raised about the need for CQC inspections and judgements to be consistent both over time and between providers.

**8 Do you have any other comments about the draft regulations?**

There were many different comments made in response to this question, relating to specific points about individual regulations, more general points about the aims, or comments summing up opinions of the proposals overall. We have addressed these comments where relevant in this response.

**9 Do you think our Impact Assessment on Fundamental Standards accurately highlights the nature and size of the costs and benefits of this proposal?**

## Requirements for registration with the Care Quality Commission: Annex B

The majority of respondents thought our impact assessment accurately highlighted the nature and size of the costs and benefits of our proposals. Many responses included comments about impact, separating out the tangible cost implications of transitioning to new regulations from the wider benefits to care of simpler and more outcome-focused regulations.

Our consultation document also included a call for further evidence on the impact of these changes, the responses to this have been used to finalise our impact assessment. The impact assessment will be published at [www.legislation.gov.uk](http://www.legislation.gov.uk), alongside the final regulations

### **10 Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?**

The vast majority of respondents had no concerns about the impact on people with protected characteristics. Some pointed out that the changes were positive in that they would apply to all users of health and adult social care services, and had a strong emphasis on person-centred care. A small number of respondents raised questions about issues faced by some groups in accessing health and care services. The views we received in answer to this question were taken in to account in an equalities screening exercise, which concluded that there would be no equalities issues.

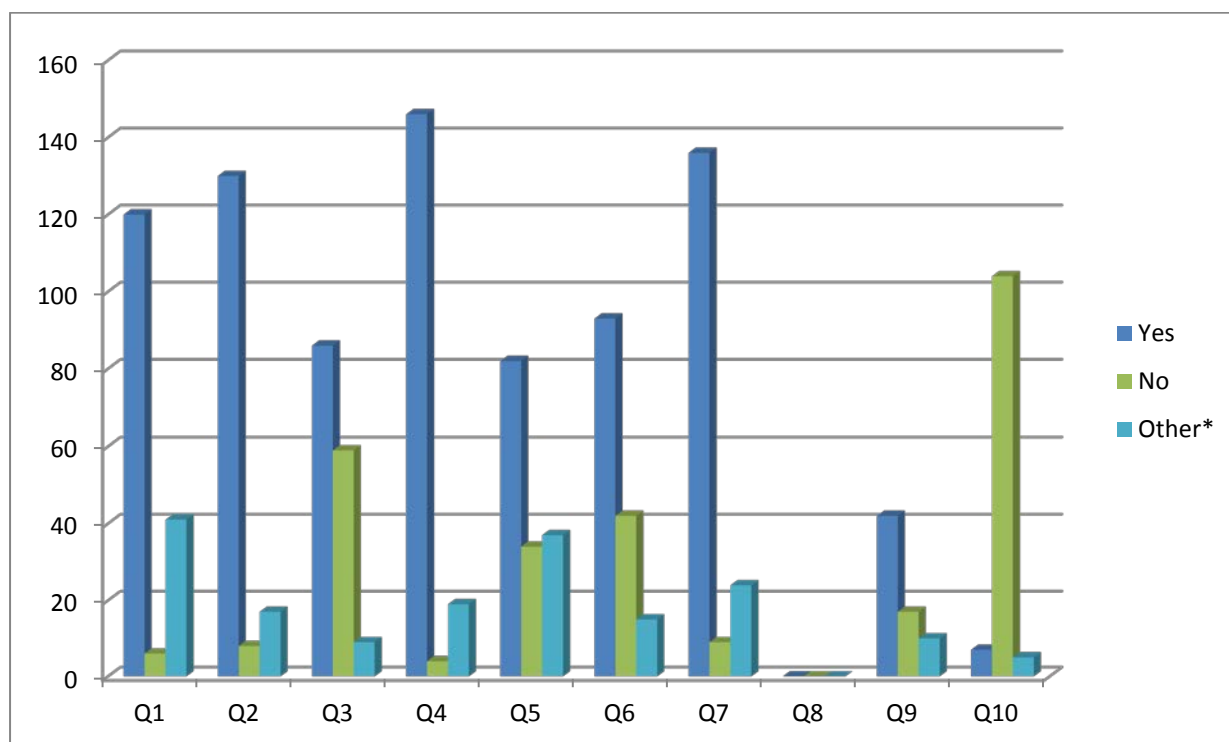
## Fundamental Standards summary of responses.

Figure 1

	Question	Yes		No		Other*	
		number	%	number	%	number	%
Q1	Do the Fundamental Standards make clear the kinds of outcomes we expect providers to meet/avoid?	120	72%	6	4%	41	24%
Q2	Do you think the Fundamental Standards regulations 4-14 reflect the policy aims we have set out for the Fundamental Standards?	130	84%	8	5%	17	11%
Q3	Do you think any changes are needed to the draft regulations to ensure they reflect the policy aims we have set out?	86	56%	59	38%	9	6%
Q4	Do you agree that the health and adult social care system should always seek to meet the standards?	146	87%	4	2%	19	11%
Q5	Are the Fundamental Standards (regulations 4-14) clear enough that they could be used as a basis for enforcement action?	82	54%	34	22%	37	24%
Q6	Regulation 17 sets out which of the regulations are offences for which CQC will still need to issue a pre-prosecution notice for, alongside those that could be prosecuted immediately. Do you think this split reflects our intention (see chapter 4) that only breaches related to a harmful outcome can be prosecuted without a pre-prosecution notice being issued in advance	93	62%	42	28%	15	10%
Q7	Do you agree that CQC's guidance about complying with these regulations should set out criteria for cases in which it would consider bringing a prosecution?	136	81%	9	5%	24	14%
Q8	Do you have any other comments about the draft regulations?	N/A	N/A	N/A	N/A	N/A	N/A
Q9	Do you think our Impact Assessment on Fundamental Standards accurately highlights the nature and size of the costs and benefits of this proposal?	42	61%	17	25%	10	14%
Q10	Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?	7	6%	104	90%	5	4%

\* responses didn't directly address the question, or were not clear either way

Figure 2



\* responses didn't directly address the question, or were not clear either way

The above charts (Figure 1 and Figure 2) show how the responses to the consultation on the fundamental standards regulations were split.

Figure 1 shows the breakdown of overall responses and responses to the ten questions:

The answers were split as follows:

**Question 1 - Do the Fundamental Standards make clear the kinds of outcomes we expect providers to meet/avoid?**

Yes: 120 agreed

No: 6 disagreed

Other: 41 responses didn't directly address the question, or were not clear either way.

**Question 2 – Do you think the Fundamental Standards regulations 4-14 reflect the policy aims we have set out for the Fundamental Standards?**

Yes: 130 agreed

No: 8 disagreed

Other: 17 responses didn't directly address the question, or were not clear either way

**Question 3 – Do you think any changes are needed to the draft regulations to ensure they reflect the policy aims we have set out?**

Yes: 86 thought yes

No: 59 thought no

Other: 9 responses didn't directly address the question, or were not clear either way

**Question 4 – Do you agree that the health and adult social care system should always seek to meet the standards?**

Yes: 146 thought yes

No: 4 thought no

Other: 19 responses didn't directly address the question, or were not clear either way

**Question 5 Are the Fundamental Standards (regulations 4-14) clear enough that they could be used as a basis for enforcement action?**

Yes: 82 said yes

No: 34 said no

Other: 37 responses didn't directly address the question, or were not clear either way

**Question 6 Regulation 17 sets out which of the regulations are offences for which CQC will still need to issue a pre-prosecution notice for, alongside those that could be prosecuted immediately. Do you think this split reflects our intention (see chapter 4) that only breaches related to a harmful outcome can be prosecuted without a pre-prosecution notice being issued in advance?**

Yes: 93 said yes

No: 42 said no

Other: 15 responses didn't directly address the question, or were not clear either way

**Question 7 Do you agree that CQC's guidance about complying with these regulations should set out criteria for cases in which it would consider bringing a prosecution?**

Yes: 136 agreed

No: 9 disagreed

Other: 24 responses didn't directly address the question, or were not clear either way

**Question 8 Do you have any other comments about the draft regulations?**

We did not undertake a quantitative analysis of this answer.

**Question 9 Do you think our Impact Assessment on Fundamental Standards accurately highlights the nature and size of the costs and benefits of this proposal?**

Yes: 42 agreed

No: 17 disagreed

Other: 10 responses didn't directly address the question, or were not clear either way

**Question 10 Do you have any concerns about the impact of the proposed regulations on people sharing protected characteristics as listed in the Equality Act 2010?**

Yes: 7 had concerns

No: 104 had no concerns

Other: 5 responses didn't directly address the question, or were not clear either way