

Mr John Culkin  
Department of Health

**By e-mail**

4 April 2014

Dear Mr Culkin

### **Fundamental Standards Consultation**

I have pleasure in responding to the consultation on behalf of the patient safety charity, Action against Medical Accidents (AvMA).

AvMA is pleased to see the approach advocated in the Francis Inquiry adopted, and we are pleased with the proposed approach and the draft standards in general. We do have some important suggestions about making the system more effective in protecting patients and staff which are set out below. We particularly welcome the commitment to add the Duty of Candour as a fundamental standard and are responding to those proposals as part of the separate consultation.

### **Distinction between Regulations and Guidance**

We note and understand the rationale for having shorter, outcome focussed fundamental standards backed up by more detailed guidance. However, we believe that care needs to be taken to ensure that the CQC is fully empowered to take regulatory action where there is a failure to comply with the guidance. We question whether the phrase "have regard to the guidance" in the regulations is sufficient to do that. A registered organisation may put forward arguments that it has had regard to the guidance but acted in ways which it believes are adequate or better to achieve the outcome.

### **Discretion for CQC to act quickly**

The regulations must allow the CQC to intervene quickly and effectively to protect patients if it finds that patients are at risk due to non-compliance with the guidance. We question the usefulness of having the requirement to go through an additional stage as provided for by regulation 17(2). We would prefer it if the CQC had discretion to act as it saw fit to protect patients, and believe that guidance on how the CQC could regulate proportionately rather than tying its hands.

Freedman House, Christopher Wren Yard, 117 High Street, Croydon, CR0 1QG.  
Tel: 020 8688 9555 | Fax: 020 8667 9065 | DX 144267 Croydon 24  
Email: [admin@avma.org.uk](mailto:admin@avma.org.uk) | Web: [www.avma.org.uk](http://www.avma.org.uk)

The regulations affected by regulation 17(2) are all as important as the other fundamental standards. We think it would be wholly inappropriate and risky for example if the CQC were not able to take the most serious immediate action if a registered organisation was operating with dangerously low staffing levels. The current regulations would force the CQC to have to go through other stages before they could.

### **Safe and Appropriate Care and Treatment**

We would like to see an addition to the regulations which made it compulsory for registered organisations to comply with Patient Safety Alerts and other alerts or notices issued by NHS England, the MHRA and other appropriate bodies. Compliance with Patient Safety Alerts in particular should be seen as an essential key component of meeting this fundamental standard and not be left to guidance which would introduce an element of discretion.

### **Support and Protection of Staff/Whistleblowers**

We would like to see the regulation amended to include a specific requirement to listen to and act upon concerns expressed by staff about the organisation's ability to comply with fundamental standards and to protect staff from adverse consequences of raising concerns. The need to support and protect staff who may otherwise need to become "whistleblowers" was a key learning point from the Mid Staffordshire Public Inquiry.

We would welcome the opportunity to take an active part in developing appropriate guidance to accompany the fundamental standards. We believe this is absolutely essential to the success of the new approach.

Yours sincerely

*Peter Walsh*

**Peter Walsh**  
**Chief Executive**