October 2014

Royal College of Surgeons

Parliamentary Briefing

Briefing for debate on the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 20: Duty of Candour

WHY DO WE NEED THE DUTY OF CANDOUR?

The College supports the proposed duty of candour. However, we stress that broader cultural change is required to facilitate greater openness in the NHS, not just procedural changes.

When things go wrong with their healthcare, patients and their families expect three things: to be told honestly what happened, what can be done to deal with any harm caused, and to know what will be done to prevent a recurrence to someone else. We believe that the duty of candour will help to address these concerns and will act as an important catalyst for organisations to improve their systems and commit to an open and learning culture for their staff.

In March 2014, the past President of the Royal College of Surgeons, Professor Norman Williams, and Sir David Dalton, chief executive of Salford Royal NHS Foundation Trust published the report of their review into how to enhance candour in the NHS. ***Building a culture of candour*** made clear that the days when errors were not disclosed must give way to an environment that allows staff to be trained and supported to admit errors, report them and learn fully from mistakes.

This briefing sets out how we think the Regulation and its implementation could be improved to ensure that the duty is understood and met.

CLARITY OF TERMS

Paragraph (7)(b)

- We believe it is in the interests of patients, families and providers of care that the duty applies to all harm that is not defined as “low”. However, we are concerned that the Government has chosen to merge the three categories, “moderate”, “severe” and “death” into a composite classification of “notifiable safety incident”. While we welcome the amalgamation of these three categories into one, which will provide simplification for organisations and their staff, we do not believe that “notifiable safety incident” is a sufficiently clear term. In addition, organisations and staff must impart information on harm to patients in a supportive way rather than as a single event of factual notification, and we believe the term “notifiable” sanitises this duty.
- At a minimum this term needs to be clarified in guidance. In the event the regulation is redrafted we encourage the Government to adopt the composite term recommended by *Building a culture of candour:* “significant harm”. This is

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easier to understand and sets a clear basis for proportionate regulatory action. However, either term will still require clear guidance and explanation to both patients and health professionals to ensure everyone understands what events should be notified.

- We believe there is value in examining measures that make it possible for patients who are judged to require a lower level response to demand a higher level response if they believe it is merited, as is possible in the Australian Open Disclosure Framework. The Australian framework includes a "Higher-Level Response" which may also be instigated at the request of the patient, even if the outcome of the adverse event is not as severe. While we accept the difficulties in adopting this approach within the proposed statutory framework, we believe the Government should give consideration to measures that provide something of the same spirit of openness to patient views and preferences.

REGULATION 23 OFFENCES: PENALTIES

- Under Regulation 23 Paragraph (6) a health service body guilty of an offence under regulation 22(3) is liable, on summary conviction, to a fine not exceeding level 4 on the standard scale (£2,500).
- It is our view that incentives that focus on reputation are more likely to be effective than those that have a financial impact. There are existing mechanisms available for incentivising candour financially, including the contractual duty of candour and the CQC's powers to levy a fine for a breach of the organisational duty of candour. We believe there is a risk of duplication if reimbursement is sought by the NHS Litigation Authority from NHS trusts which have already been investigated by the CQC and/or regulatory action taken, and where a contractual fine may have been levied by commissioners. We are also concerned that applying financial penalties will take resources away from frontline NHS and social care organisations that are already facing unprecedented financial pressures.

ENSURING THE LEGAL SYSTEM SUPPORTS THE DUTY

- While the NHS Litigation Authority has made clear that it will continue to indemnify organisations that apologise and explain to patients, it is the case under current law that explanations can be used as evidence of admissions of liability. This can have the effect of discouraging candour because of the fear that what is said can be used in negligence litigation. We believe the Government must consider how it can ensure that the legal system is most able to support a culture of candour. In particular, it could be helpful to minimise the possibility that explanations given as part of a process of candour are then used in evidence to support an admission of negligence.

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