MEETING:	**PUBLIC BOARD MEETING** **23 September 2015**
Agenda item and Paper Number	**7** **CM/09/15/07**
Agenda Title	**Duty of Candour**
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PURPOSE OF PAPER:

Actions required by the Board

- **To note** the current status of implementation of the Duty of Candour regulation and the progress made to date
- **To endorse** the proposal for CQC to further clarify the aims and implications of the the Duty and to strengthen our approach to assessing implementation through our approach to inspection.

1. Summary

The purpose of this report is to outline the current status of Regulation 20: Duty of Candour and to note lessons learnt to date.

This regulation (Annex A) was introduced on 27 November 2014 for NHS bodies and on 1 April 2015 for all other providers regulated by CQC. The duty requires providers to be open with people using services when they experience harm, including harm arising from known risks.

Whilst the aim of the regulation is to encourage a more open and transparent culture whenever people are harmed by services, it also prescribes a number of clear steps that must be followed when a notifiable safety incident occurs. With the introduction of a criminal sanction, this has prompted a focus on specific incident types and reporting thresholds. Feedback to date suggests that further information and guidance is needed to improve understanding amongst providers and the public.

Following the introduction of the regulation, the Department of Health (DH) was made aware of a number of potential issues in relation to the different prescribed thresholds for triggering the duty for NHS bodies and other providers. In response, the DH has committed to consulting on the issues in the Autumn. Whilst it remains to be seen if this will result in a change in the regulations, further guidance may be required for providers and our inspection staff. We continue to liaise closely with DH.

2. Recommendation

It is recommended that the Board endorses the following proposed actions for completion during 2015/16:

- We will provide further guidance for inspection teams explaining what to look for during inspections and how the Duty of Candour should be reported on
- We will work with our partners, including DH, to promote understanding of the regulation amongst stakeholders by:
    - providing information for the public on what to expect from the Duty and the circumstances under which they may want to raise concerns with providers or with us;
    - revising CQC's guidance and issuing this and other communications to providers and inspectors to clarify issues which have arisen to date and those which may emerge as part of DH's consultation;
    - clarifying the roles and responsibilities that providers and other national and local partners share, alongside CQC, in embedding the Duty and supporting a more open culture across the health and care system.

3. Discussion and Implications

3.1 Background

The Duty of Candour was introduced following a recommendation by Sir Robert Francis QC in the report of his inquiry into the failings at Mid Staffordshire NHS Foundation Trust. It was included as one of two new regulations within the new fundamental standards for registered providers introduced in November 2014 for NHS bodies and in April 2015 for all other providers (the other new regulation was the Fit and Proper Persons regulation).

The Duty of Candour regulation prescribes a number of clear steps that must be followed when a notifiable safety incident occurs, and it defines such incidents for both NHS bodies and all other providers. The relevant person (the 'service user', or where appropriate, their representative) must be notified as soon as reasonably practicable when a safety incident has occurred, and they must be given appropriate support and a written apology. The regulation defines 'notifiable safety incidents' for NHS bodies and all other providers in line with pre-existing reporting requirements.

CQC's role is to oversee and enforce the regulation in all sectors, and we do this through our comprehensive inspections in every sector and by responding to any information of concern that we receive. In advance of the introduction of the duty, CQC developed guidance for providers and for CQC inspection staff. We adopted our initial inspection approach following discussion with DH. This involves checking whether organisations have developed robust systems and processes to meet the statutory requirements and to support an open culture. Additional, more detailed inspection work was reserved for providers where the evidence indicated they may be deliberately avoiding transparency.

Since the implementation of the Duty, we have found that further guidance and information is needed for providers, the public and for CQC inspection teams. This

is necessary to clarify what providers are required to do to meet the Duty of Candour and what the public can expect when things go wrong in their health or social care. It will also help CQC inspection teams to further embed the requirements of the Duty into our inspection approach.

We have now started a more formal evaluation to enable us to understand what further information and support is needed for providers, the public and our staff, but we outline some of the evidence from the early implementation of the Duty below.

3.2 Guidance for providers and the public

The evidence to date suggests that further clarity is needed for providers and the public about incidents which trigger the duty.

As the April 2015 implementation date approached for adult social care, primary medical and dental services and independent health, we received a high number of queries and requests for clarification. This indicated that there was uncertainty about the scope of the regulation, the thresholds for triggering the Duty, and its impact on pre-existing reporting practices.

CQC responded to individual queries, but did not issue any further guidance at this time. The clarifications provided were in line with our existing guidance and we wanted to avoid the risk of confusion by issuing new guidance. In light of the evidence that there continues to be uncertainty, it would be helpful to develop further internal and external guidance and information and to work with our partners to make sure that all are providing a consistent message.

Key messages will include:

- The aim of the regulation is to encourage a more open culture in the way that providers communicate with people using services whenever they are harmed.
- Demonstrating an open culture does however not guarantee compliance with the regulation, which prescribes specific communication, reporting and recording requirements in relation to notifiable safety incidents.
- The Duty applies not just to incidents caused by ‘mistakes’ or ‘failings in care’ but to all notifiable safety incidents that result in harm, even if these arise from known risks.

We will continue to work with stakeholders to understand their questions and concerns and will develop more examples of the different types of incident that should trigger the Duty. We will work with our partners, including the Department of Health and the professional regulators, to make sure that we are providing a consistent explanation of the Duty as it applies to organisations and to professionals. This will include explaining the roles and responsibilities that other national and local partners, including commissioners and regulators, play in supporting the implementation of the Duty and developing a more open culture across health and social care.

It will also include developing clearer information for the public to explain what they can expect from the Duty and the circumstances under which they may want to raise concerns with providers or with CQC.

3.3 Inspecting the Duty of candour

We have recently started to evaluate how the Duty of Candour is being implemented in our inspections. To date, we have not identified a breach of regulation 20.

An initial analysis of relevant inspection reports would appear to indicate that the Duty of Candour is reported directly most often in our hospital sector inspection reports. Reports in adult social care, primary medical care and independent health do contain information about complaints handling, communications, transparency and whether people affected by significant events received a timely and sincere apology, all of which are at the heart of the Duty. We will therefore now undertake further qualitative analysis of inspection reports to further understand the level of coverage and to identify emerging themes.

We will also be sampling relevant safety incidents in three forthcoming Hospitals inspections, with a view to developing a simple, practical method for assessing the implementation of the Duty. We will use the findings of this pilot and our evaluation to develop a method for use by teams in all our inspections. This will help to ensure that we are inspecting and reporting the Duty of Candour in a consistent way in every sector.

3.4 Department of Health consultation

The Department of Health has committed to undertaking a consultation about the regulation in the Autumn. One of the issues which led to this response was concern about the minor differences in pre-existing reporting thresholds between private and NHS providers that was highlighted by the introduction of the regulation.

Providers were clear during consultation that they would prefer the Duty of Candour to align with existing definitions of safety incidents, rather than work to new definitions. However the introduction of the regulation highlighted this discrepancy and indicated that some GPs are reporting incidents to the National Reporting and Learning System (NRLS) *instead* of to CQC, which is in breach of the legal requirement to notify CQC.

We are not proposing any specific changes to the regulation, but we will be working with DH during their consultation to help identify and resolve issues of concern and ensure they are reflected in our guidance.

We will also work with DH and NHS England to address the issue of non-compliant reporting practices. A change in reporting requirements could usefully be considered to bring primary care into line with the wider use of NRLS as the main system for reporting incidents in the NHS.

Any communication by CQC on the Duty of Candour will be planned to avoid confusion with DH messaging regarding their consultation.

4. Conclusion and Next Steps

The implementation of Regulation 20 is still in its early stages following its introduction in November 2014 for NHS bodies and April 2015 for all other providers.

Work is in hand to further embed our approach to assessing and reporting the Duty in our inspections and to resolve some remaining issues before the end of this financial year. DH intends to consult on the regulation this Autumen, and CQC will continue to work closely with DH to clarify providers' issues of concern and to develop clearer guidance for providers, the public and our staff.

Appendices

Annex A – Regulation Duty of Candour

Background Papers

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Annex A: Regulation 20 Duty of Candour

1. Registered persons must act in an open and transparent way with relevant persons in relation to care and treatment provided to service users in carrying on a regulated activity.
2. As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a registered person must—
    a. notify the relevant person that the incident has occurred in accordance with paragraph (3), and
    b. provide reasonable support to the relevant person in relation to the incident, including when giving such notification.
3. The notification to be given under paragraph (2)(a) must—
    a. be given in person by one or more representatives of the registered person,
    b. provide an account, which to the best of the registered person's knowledge is true, of all the facts the registered person knows about the incident as at the date of the notification,
    c. advise the relevant person what further enquiries into the incident the registered person believes are appropriate,
    d. include an apology, and
    e. be recorded in a written record which is kept securely by the registered person.
4. The notification given under paragraph (2)(a) must be followed by a written notification given or sent to the relevant person containing—
    a. the information provided under paragraph (3)(b),
    b. details of any enquiries to be undertaken in accordance with paragraph (3)(c),
    c. the results of any further enquiries into the incident, and
    d. an apology.
5. But if the relevant person cannot be contacted in person or declines to speak to the representative of the registered person —
    a. paragraphs (2) to (4) are not to apply, and
    b. a written record is to be kept of attempts to contact or to speak to the relevant person.
6. The registered provider must keep a copy of all correspondence with the relevant person under paragraph (4).
7. In this regulation—
    "apology" means an expression of sorrow or regret in respect of a notifiable safety incident; "moderate harm" means—
    a. harm that requires a moderate increase in treatment, and
    b. significant, but not permanent, harm;

    "moderate increase in treatment" means an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care);
    "notifiable safety incident" has the meaning given in paragraphs (8) and (9);
    "prolonged pain" means pain which a service user has experienced, or is likely to

experience, for a continuous period of at least 28 days;
"prolonged psychological harm" means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
"relevant person" means the service user or, in the following circumstances, a person lawfully acting on their behalf—

c. on the death of the service user,
d. where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
e. where the service user is 16 or over and lacks capacity in relation to the matter;

"severe harm" means a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

8. In relation to a health service body, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in—
    a. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
    b. severe harm, moderate harm or prolonged psychological harm to the service user.
9. In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional—
    a. appears to have resulted in—
        i. the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition,
        ii. an impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for a continuous period of at least 28 days,
        iii. changes to the structure of the service user's body,
        iv. the service user experiencing prolonged pain or prolonged psychological harm, or
        v. the shortening of the life expectancy of the service user; or
    b. requires treatment by a health care professional in order to prevent—
        i. the death of the service user, or
        ii. any injury to the service user which, if left untreated, would lead to one or more of the outcomes mentioned in sub-paragraph (a).