Department of Health

Introducing the Statutory Duty of Candour

A consultation on proposals to introduce a new CQC registration regulation

March 2014

Title: Introducing the Statutory Duty of Candour
Author: Strategy and External Relations Directorate/ Quality Regulation/ 17160
Document Purpose: Consultation
Publication date: March 2014
Target audience: Department of Health Arm's Length Bodies Providers of healthcare and adult social care registered with the Care Quality Commission The General Public
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Published to gov.uk, in PDF format only.

www.gov.uk/dh

Introducing the Statutory Duty of Candour

A consultation on proposals to introduce a new CQC registration regulation

Prepared by the Department of Health

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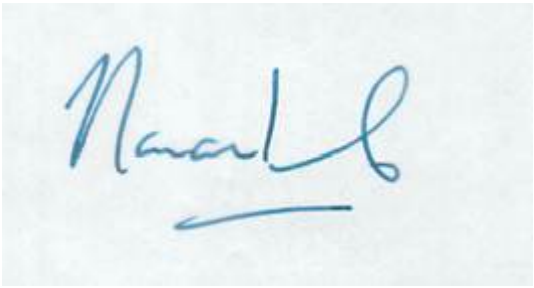
Foreword

When we published *Hard Truths* in November 2013, we said that we wanted people to have confidence that they will be given the best and safest care. There is now a real commitment to greater openness and candour, to developing a culture dedicated to learning and improvement that continually strives to reduce avoidable harm. We are determined to build on this commitment, and to make openness and transparency a cornerstone of our approach. The leadership shown by Professor Norman Williams and Sir David Dalton in making such a compelling case for candour provides an excellent start for making a new culture happen. This document builds on their work. It presents and describes the draft regulations that will make candour a reality. I hope that providers, people who use services and their families will again respond to this consultation as we develop the regulations.



Norman Lamb
Minister for Care and Support

1. Introduction

This consultation sets out a proposed addition to the requirements for registration[1] with the Care Quality Commission (CQC) in order to introduce a statutory Duty of Candour on all providers registered with the CQC.

The introduction of a statutory Duty of Candour is a major step towards implementing a key recommendation from the Mid Staffordshire NHS Foundation Trust Public Inquiry (the Francis Inquiry). The Duty of Candour will place a requirement on providers of health and adult social care to be open with patients when things go wrong. Providers should establish the duty throughout their organisations, ensuring that honesty and transparency are the norm in every organisation registered by the CQC.

The Duty of Candour will be part of the new set of registration requirements that together will set out the clear outcomes that providers must meet, which will be core to good service provision. This consultation on the statutory Duty of Candour follows on from a separate consultation on regulations that will introduce the fundamental standards of care[2]. Subject to Parliamentary approval, all these registration requirements will become part of the same consolidated package of regulations, to be introduced in October 2014.

This consultation document sets out in more detail the policy thinking behind the new statutory Duty of Candour. It summarises previous consultations and reviews, and links these reviews to what we are proposing in the draft regulations.

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[1] The current registration requirements are laid down in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010

[2] Introducing Fundamental Standards: consultation on proposals to change CQC registration regulations, Department of Health, January 2014 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/274715/Introducing_Fundamental_Standards_-_a_Consultation.pdf

2. Previous Reviews and Consultations

The Francis Inquiry

The Francis Inquiry[3] concluded that there seems to be a near universal agreement that candour is an essential component in high quality healthcare, but that openness, transparency and candour are frequently not observed. The Report made a number of recommendations about the Duty of Candour that can be summarised as follows:

- healthcare providers should be under a statutory Duty of Candour to inform the patient, or other duly authorised person as soon as practicable, when they believe or suspect that treatment or care it provided has caused death or serious injury to that patient, and thereafter provide such information and explanation as the patient reasonably may request;

- there should be a statutory Duty of Candour on registered healthcare professionals to inform their employer where they believe or suspect that treatment has caused death or serious injury and;

- It should be a criminal offence for any registered medical practitioner, or nurse or allied health professional or director of an authorised or registered healthcare organisation to knowingly obstruct another in the performance of these statutory duties, provide information to a patient or nearest relative with the intent to mislead them about such an incident or dishonestly make an untruthful statement to a commissioner or regulator, knowing or believing that they are likely to rely on the statement in the performance of their duties.

The Francis Inquiry also noted that observance of the duty should be policed by the CQC. In the Government's initial response[4] to the Francis Inquiry, published in March 2013, we accepted the need to introduce a statutory Duty of Candour for health and care providers.

CQC Consultation and the Berwick Review

The Government's initial response was followed by a CQC consultation[5] on the way it regulates, inspects and monitors care, which included questions about the planned statutory Duty of Candour. In its response to the consultation, CQC noted that there was strong support for the introduction of a Duty of Candour, particularly from the public and acute providers. They felt it

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[3] The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, February 2013 - http://www.midstaffspublicinquiry.com/report

[4] Patients First and Foremost: the Initial Government Response to the Report of The Mid Staffordshire NHS Foundation Trust Public Inquiry, Department of Health, March 2013 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

[5] A new start: consultation on changes to the way CQC regulates, inspects and monitors care, Care Quality Commission, June 2013 - http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

would increase public confidence and introduce accountability across all sectors. There was a desire for more information about how and when the Duty would apply and for clarification on the definitions. Some respondents were concerned that the Duty of Candour would hinder a learning environment as people would not be open and honest about near misses or serious incidents, especially if individuals were prosecuted as a result.[6]

The Berwick Review[7], published in August 2013, also recommended that, for serious incidents, CQC regulations should require that the patient or carer affected by a safety incident is notified and supported. However, the Berwick Report did not subscribe to an 'automatic' Duty of Candour, where patients are told about every error or near miss, as this would lead to defensive documentation and large bureaucratic overheads that detract from patient care.

Hard Truths

The Statutory Duty of Candour

The Government provided a detailed response to the Francis Inquiry in *Hard Truths: the Journey to Putting Patients First*. We agreed that the Government would introduce an explicit Duty of Candour as a CQC registration requirement. It was accepted that the duty would apply to health and adult social care providers of regulated activities and would be enforced using CQC's enforcement powers. We also agreed to consult on the regulations setting out this duty, which would require providers to inform people of the incident, provide an explanation, and, where appropriate, an apology.

Professional Regulation

Hard Truths acknowledged that the professional values of individual clinicians are critical in ensuring an open culture in which mistakes are reported, but also said the Government did not intend to introduce any candour-related offences on individuals. Instead, the professional regulators are working to strengthen references to candour in their guidance. Regulated health and care professionals will have to be candid with patients/service users about all avoidable harm, and obstructing colleagues in being candid will be a breach of the professional codes. Professional regulators will also review their guidance to professional misconduct panels to ensure they take proper account of whether professionals have raised concerns promptly. This work complements the statutory Duty of Candour but is now being taken forward by the professional regulators.

The Dalton Williams Review

In Hard Truths, we indicated that the Department would seek advice from experts on how to improve the reporting of patient safety incidents, including whether or not the Duty of Candour

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[6] A new start: responses to our consultation on changes to the way CQC regulates, inspects and monitors care services, Care Quality Commission, October 2013 - http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

[7] A promise to learn – a commitment to act: improving the safety of patients in England, August 2013 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

requirements should cover death and serious injury, or death, serious injury and moderate harm. The Secretary of State subsequently invited Sir David Dalton, Chief Executive of Salford Royal NHS Foundation Trust and Professor Norman Williams, President of the Royal College of Surgeons, to conduct a review of the threshold for the new duty and the possibility of adjustments to NHS indemnity cover. This consultation focuses on the former issue only.

The Review concluded that the statutory Duty of Candour requires a culture of candour. This in turn requires:

- training and support for staff to disclose information about unanticipated events in a patient's care and apologise when appropriate;
- improvements in the levels and accuracy of the reporting of patient safety incidents;
- spreading and applying lessons learned into practice and publicly reporting these.

This Review took evidence from a wide range of stakeholders including patient advocate groups, professional organisations and academics.[8] The scope of the Dalton Williams Review was limited to healthcare. It concluded that the Duty of Candour should apply to all cases of 'significant harm'. This new composite classification would cover the National Reporting and Learning System categories of 'moderate', 'severe' and 'death', but would also include 'prolonged psychological harm'.

The Department accepts the recommendation that the threshold for the duty of candour in the NHS should include death, severe and moderate harm, as well as prolonged psychological harm. The rest of this consultation explains how this has been translated into draft regulations and asks for views on a number of key issues.

Think Local Act Personal Review

As the Dalton Williams Review considered healthcare, a piece of work on the Duty of Candour from an adult social care perspective was undertaken by the Think Local Act Personal partnership (TLAP), supported by the Department of Health[9]. The conclusions of this work are broadly similar to those emerging from the Dalton Williams Review. Key findings included:

- A statutory Duty of Candour would support improvements in openness and transparency so long as the linkages with existing frameworks are clear.

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[8] Building a Culture of Candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid, March 2014 - http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf

[9] The Duty of Candour – an Adult Social Care Perspective, Think Local Act Personal, March 2014 - http://www.thinklocalactpersonal.org.uk/_library/The_Duty_of_Candour_-_an_Adult_Social_Care_Perspective_March_2014.pdf

- The Duty of Candour was seen as a mechanism to support cultural change, particularly for providers who have not fully embedded a bottom-up approach to openness and transparency as part of continuous improvement processes;

- There was broad support for the inclusion of death and serious injury, as outlined in the current CQC notification requirements[10], within the harm threshold. The possibility of placing the harm threshold at some lower-level was also generally supported.

[10] See regulations 16 and 18 of the Care Quality Commission (Registration) Regulations 2009.

3. What we are Proposing in the Statutory Duty of Candour Regulations

Primary and Secondary Legislation

At present there is a contractual Duty of Candour on organisations that provide services under the NHS Standard Contract. The Government is committed to going further and implementing a statutory Duty of Candour across a much wider range of providers. The Care Bill will place a specific duty on the Government to include a Duty of Candour on providers registered with the Care Quality Commission. This means that, subject to the passage of the Bill, a statutory duty of candour must always be one of the registration requirements placed on CQC registered providers. The Duty of Candour itself will be set out in secondary legislation in regulations. The draft Duty of Candour regulations are at Annex A and explained further below.

The draft regulations require all providers registered with CQC, both healthcare and adult social care providers, to be open and transparent with service users about their care and treatment. The regulations also impose a more specific and detailed Duty of Candour on all providers where any harm to a service user from their care or treatment is above a certain harm-threshold.

Harm Thresholds

For Healthcare

In the regulations, the harm threshold for healthcare is set at the threshold recommended by Dalton/Williams to include 'moderate' harm. This means that all harm that is classified as moderate or severe or where 'prolonged psychological harm' has arisen gives rise to a Duty of Candour to the service user, or a person lawfully acting on their behalf. The Duty will also apply in cases of death, if the death relates to the incident of harm rather than to the natural course of the service user's illness or underlying condition. The advantage of using this threshold is that it is the same as the harm threshold used in the contractual Duty of Candour in the NHS Standard Contract (with the exception of the inclusion of 'prolonged psychological harm). CQC will also normally be notified of these incidents that occur in NHS-funded care via reporting to the existing National Learning and Reporting System (NRLS).

For Adult Social Care

The definitions of 'moderate' and 'severe' harm in the Dalton/Williams report mirror those used in relation to the NRLS (with the exception of prolonged psychological harm). These definitions are focussed on healthcare, as the NRLS is a system used to report healthcare patient safety incidents. As such, the NRLS definitions and supporting illustration do not apply directly to adult social care providers. Given the NRLS definitions were not created for a social care setting we intend to use the existing CQC notification requirement for 'serious injuries' as the Duty of

Candour harm threshold for adult social care. The notification requirement for serious injury is broadly similar in scope: CQC has indicated that it covers the 'severe' and some of the 'moderate' harm categories recommended by Dalton Williams. It also covers prolonged psychological harm. Thus for adult social care providers, the duty will apply to death, serious injury, some moderate harm and prolonged psychological harm, broadly consistent with the application in the NHS.

Do you have any comments on the Duty of Candour harm threshold chosen for healthcare?

Do you have any comments on the Duty of Candour harm threshold chosen for adult social care?

Duty of Candour Reporting Requirements

The regulations outline that, where the harm threshold has been breached, specific reporting requirements need to be followed. In summary, the service provider would need to:

- notify the service user (which includes someone lawfully acting on their behalf where necessary) that the incident has occurred. This notification will include an apology;
- advise and if possible agree with the service user what further enquiries are appropriate;
- provide all information directly relevant to the incident;
- provide reasonable support to the service user;
- inform the service user in writing of the original notification and the results of any further enquiries.

Do you agree with the requirements to be placed on service providers under the Duty of Candour?

CQC Guidance and Enforcement

The regulations also state that the service provider must have regard to any guidance issued by the CQC. The Dalton Williams Review stated that: 'we have sought to set out a threshold that provides the clarity organisations need, and a basis for proportionate regulatory action by the CQC'. They also noted that they had 'sought to align our approach with existing frameworks and reporting systems so that organisations are able to graft their approach to candour onto existing processes and systems'[11]. Following this approach, we think it should be possible to put in place an organisational duty of candour that can be clearly understood and applied by

[11] Both references in the paragraph refer to the Dalton Williams Report, Chapter 2, paragraph 27.

care organisations, and used as a catalyst or reinforcement for developing a wider culture of safety, learning and improvement.

CQC will issue draft guidance on the new registration requirements and this will take account of the review and the comments received by way of this consultation.

Where the duty has been breached, CQC will have available its full range of enforcement powers. However, we would expect CQC to use its powers proportionately in all cases. CQC has enforcement powers against the service provider, but has no powers to provide individual service users with redress.

Costs of the Duty of Candour

Our initial assessment of the costs and benefits of our proposal for a statutory Duty of Candour can be found in the Impact Assessment available alongside this consultation. This assessment comes to the strong conclusion that a Duty of Candour is needed to create a consistent standard across all providers. The assessment was based on an earlier version of the threshold that does not fully cover moderate harm in healthcare. Additional work is being undertaken in this area, and we have included a call for evidence in Annex C to help us further understand the likely impact of the changes, including the benefits.

Do you have any views on the costs and benefits associated with the Duty of Candour as set out in the draft impact assessment (published alongside this document)? See Annex C for more detailed questions on impact.

4. Equality Issues

Section 149 of the Equality Act 2010 establishes the Public Sector Equality Duty (PSED), requiring a public authority in the exercise of its functions to have due regard to the need to:

- eliminate discrimination, harassment, victimisation and any other conduct prohibited in the 2010 Act;
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

Section 149(7) of the 2010 Act describes “relevant protected characteristics” for the purpose of the PSED as: age; disability; gender reassignment; pregnancy and maternity; race; religion or belief; sex; and, sexual orientation. It also specifies that Ministers of the Crown and government departments are public authorities for the purpose of the PSED.

Thus, in the development of the new offence discussed in this consultation document, we must ensure that we have due regard to the obligations placed upon Ministers by the PSED, and other duties on the Secretary of State. In parallel with this consultation, we are conducting an initial screening exercise which seeks to identify the scope of those who may be affected and whether the proposed policy may have equality impacts for affected persons who share a protected characteristic. We are also using this consultation exercise to obtain the views of stakeholders on possible impacts to inform the screening exercise and, if appropriate, a full equality impact assessment.

Do you think any of the proposals set out in this consultation document could have equality impacts for affected persons who share a protected characteristic, as described above? If so, please tell us about them.

(The relevant protected characteristics are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.)

5. How to Respond

This section outlines the ways in which you can respond to this consultation.

In this document we have set out our aims and intentions to increase openness and transparency through the introduction of a new statutory Duty of Candour on CQC registered providers. **The consultation questions are set out in Section 4 above and Annex B. The draft regulations can be found at Annex A.**

This consultation concludes our engagement on the Duty of Candour. We have already taken account of views on the Duty of Candour submitted in response to the earlier CQC consultation, as well as evidence submitted in response to the Francis Inquiry and evidence submitted during the passage of the Care Bill. In addition, the review chaired by Sir David Dalton and Professor Norman Williams took evidence from a wide range of healthcare stakeholders, whilst Think Local Act Personal have published a paper, looking at the Duty of Candour from an adult social care perspective. The draft regulations at Annex A take account of all this feedback, particularly the work of the Dalton Williams Review and the Think Local Act Personal partnership. It is therefore our intention to consult on the regulations for four weeks, closing on **25 April 2014.**

In response to this consultation, you can:

Answer the questions online at: http://consultations.dh.gov.uk/standards/duty-of-candour

Email your response to: Dutyofcandourconsultation@dh.gsi.gov.uk

Post your responses to:

Duty of Candour Consultation
c/o Jeremy Nolan
Room 2E11
Quarry House
Quarry Hill
Leeds
West Yorkshire
LS2 7UE

An **Easy Read** version of this document is available on line at:
http://consultations.dh.gov.uk/standards/duty-of-candour

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please:

contact: Consultations Coordinator
Department of Health
2E11, Quarry House
Leeds
LS2 7UE

or e-mail : consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter**[12]**.**

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

[12] http://transparency.dh.gov.uk/dataprotection/information-charter/

Annex A – Draft Regulations

Draft Order laid before Parliament under section 162(3)(b) of the Health and Social Care Act 2008, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2014 No. 000

NATIONAL HEALTH SERVICE, ENGLAND

SOCIAL CARE, ENGLAND

PUBLIC HEALTH, ENGLAND

Health and Social Care Act 2008 (Duty of Candour) Regulations 2014

Made - - - -	***
Coming into force - -	*1st October 2014*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 20 and 161(3) of the Health and Social Care Act 2008([1]).

In accordance with section 20(8) of that Act, the Secretary of State has consulted such persons as the Secretary of State considers appropriate.

A draft of these Regulations was laid before Parliament in accordance with section 162(3)(b) of the Health and Social Care Act 2008, and was approved by a resolution of each House of Parliament.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Health and Social Care Act 2008 (Duty of Candour) Regulations 2014 and come into force on 1st October 2014.

(2) In these regulations—

"the Act" means the Health and Social Care Act 2008;

"apology" means an expression of sorrow or regret in respect of a notifiable safety incident;

([1]) 2008 c. 14.

"health care professional" means a person who is registered as a member of any profession to which section 60(2) of the Health Act 1999([2]) (regulation of health professions, social workers, other care workers, etc) applies;

"moderate harm" means—

(a) a moderate increase in treatment,

(b) significant, but not permanent, harm, or

(c) prolonged psychological harm;

"moderate increase in treatment" means a 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" is to be interpreted in accordance with paragraphs (3) to (5);

"prolonged pain" or "prolonged psychological harm" means pain or (as the case may be) psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

"registered manager" means, in respect of a regulated activity, a person registered with the Commission([3]) under Chapter 2 of Part 1 of the Act as a manager in respect of that activity;

"registered person" means, in respect of a regulated activity, a person who is the service provider or registered manager in respect of that activity;

"relevant person" means the service user or, where the service user is not competent to make a decision in relation to their care or treatment, a person lawfully acting on their behalf;

"safety incident" means any unintended or unexpected incident that occurs, or is suspected to have occurred, in respect of a service user during the provision of a regulated activity that could result in, or appears to have resulted in, harm to the service user;

"service provider" means, in respect of a regulated activity, a person registered with the Commission under Chapter 2 of Part 1 of the Act as a service provider in respect of that activity;

"service user" means a person who receives services provided in the carrying on of a regulated activity;

"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.

(3) In relation to the provision of health care services, "notifiable safety incident" means a safety incident that appears to have resulted in—

(a) the death of the service user, where the death relates to the incident rather than to the natural course of the service user's illness or underlying condition, or

(b) severe harm or moderate harm to the service user.

(4) In relation to the provision of social care services, "notifiable safety incident" means a safety incident which, 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 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

([2]) 1999 c. 21.

([3]) By section 1(1) of the Health and Social Care Act 2008, "the Commission" means the Care Quality Commission.

(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).

(5) Where a service is both a health care service and a social care service, paragraph (3) is to apply.

General

2. A registered person must comply with regulation 3 in carrying on the regulated activities in respect of which they are registered.

Duty of candour

3.—(1) The registered person must act in an open and transparent way with relevant persons in relation to the service user's care and treatment.

(2) As soon as practicable after becoming aware that a notifiable safety incident has occurred the registered person must—

(a) in accordance with paragraph (3), notify the relevant person that the incident has occurred,

(b) provide the relevant person with all information directly relating to the incident, and

(c) provide reasonable support to the relevant person in relation to the incident.

(3) The notification to be given under paragraph (2)(a) must—

(a) be conducted in person by one or more representatives of the service provider,

(b) be recorded in writing,

(c) provide a truthful account of all the facts the service provider knows about the incident as at the date of the notification,

(d) advise and, if possible, agree with the relevant person what further enquiries into the incident are appropriate,

(e) include an apology, and

(f) be followed in writing by—

(i) a notification in accordance with sub-paragraphs (c) to (e), and

(ii) the results of any further enquiries into the incident.

(4) But where the relevant person cannot be contacted in person or declines to speak to the representative of the service provider—

(a) paragraph (2)(a) and (c) is not to apply, and

(b) paragraph (2)(b) is to be read as requiring a record to be kept of attempts to contact or speak to the relevant person.

(5) The registered person must keep a copy of all correspondence with the relevant person under paragraph (3)(f).

Compliance with regulations 2 and 3

4. Where there is more than one registered person in respect of a regulated activity, or in respect of that activity as carried on, at or from particular premises, anything which is required under regulations 2 and 3 to be done by the registered person is not, if done by one of the registered persons, to be required to be done by any of the other registered persons.

Guidance

5. For the purposes of compliance with the requirements set out in these Regulations, the registered person must have regard to guidance issued by the Commission under section 23 of the Act in relation to the requirements set out in regulations 2 and 3.

Offence

6.—(1) A breach of regulations 2 and 3 is an offence.

(2) A person guilty of an offence under paragraph (1) is liable, on summary conviction, to a fine.

(3) In any proceedings for an offence under this regulation, it is a defence for the registered person to prove that they took all appropriate steps and exercised all due diligence to ensure that the provision in question was complied with.

Signed by the authority of the Secretary of State for Health

Name
Minister of State
Department of Health

00th ***** 2014

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for a new requirement that will apply in relation to the way in which regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 are carried on. Regulation 3 lays down a new duty of candour on registered persons.

Regulation 3(1) requires registered persons to be open and transparent with service users in relation to their care and treatment. Regulation 3(2) requires registered persons to notify service users, or their legal representatives, when a safety incident appears to have resulted in harm to the service user of the type specified in regulation 1(3), in the case of health care services, or regulation 1(4), in the case of adult social care services.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health) and is published alongside this instrument and its Explanatory Memorandum at www.legislation.gov.uk.

Annex B – Consultation Questions

Threshold

1 Do you have any comments on the Duty of Candour harm threshold chosen for healthcare?

2 Do you have any comments on the Duty of Candour harm threshold chosen for adult social care?

Requirements on providers

3 Do you agree with the requirements to be placed on service providers under the Duty of Candour?

Costs

4 Do you have any views on the costs and benefits associated with the Duty of Candour as set out in the draft impact assessment (published alongside this document)? See Annex C for more detailed questions on impact.

Equalities

5 Do you think any of the proposals set out in this consultation document could have equality impacts for affected persons who share a protected characteristic, as described below? If so, please tell us about them.

(The relevant protected characteristics are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.)

Annex C – Assessing the Impact of these Changes

Duty of Candour

Do you currently have a specific policy on being honest and candid with patients or service users when things go wrong?

Yes ☐ No ☐

If yes, how much time do you spend referring to or using that policy?

0-2 hours a month ☐

2-4 hours a month ☐

4-8 hours a month ☐

Over 8 hours a month ☐

Will you have to change (or introduce) any policies or practices as a result of the proposed Duty of Candour?

Yes ☐ No ☐

In your opinion, which of the impacts listed below can/do result from being open and honest?

Improved reputation ☐

Improved safety ☐

Reductions in future errors ☐

Improved staff morale ☐

Improved patient satisfaction ☐

Reduction in formal complaints ☐

Any others? Click here to enter text.

What impact do you think the proposed Duty of Candour would have on private sector General Practitioner and dental practices?

Click here to enter text.

How do you think the proposed Duty of Candour would affect the workload of those delivering and managing the provision of care?

Click here to enter text.

What impact do you think the proposed Duty of Candour would have on insurance costs?

Click here to enter text.

Do you have any examples you can share about how being open and honest can benefit your business?

Click here to enter text.

Do you think our Impact Assessment on Duty of Candour accurately highlights the nature and size of the costs and benefits of this proposal?

Yes ☐ No ☐