Policy Title	Duty of Candour
CQC KLOE Reference	Well Led

Policy

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 states:

20.*— (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 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;
"prolonged pain" means pain 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—
(a) on the death of the service user,
(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
(c) 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 a registered person who is not 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—
(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,
(a) (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) .

The Agency fully accepts its responsibility to be open and honest with Clients and other relevant persons (people acting lawfully on the behalf of Clients) when things go wrong with care and treatment, and to provide them with reasonable support, truthful information and a written apology.

To meet the requirements of this Regulation, the Agency will promote (through training, education, and acting as a role model) an open and honest culture across and at all levels within its organisation and will ensure that it has systems in place which demand the reporting, internally, and without delay, of ***notifiable safety incidents***. (see Paragraph 9 above).

In reporting to Clients and other relevant persons the Agency will:

(a) communicate what has happened as soon as practicable (this means as soon as possible after the discovery or occurrence of a notifiable safety incident);
(b) provide a truthful account of the incident; and
(c) an explanation in writing about the enquiries and investigations that will be undertaken and offering an apology in writing.

This account should be given in a manner which is jargon-free and capable of being understood by the person concerned.

Where the Client affected by an incident lacks capacity, or it is felt that it would be counterproductive to disclose information, appropriate arrangements should be in place to support best interest decisions and relevant persons are notified.

Where the Agency becomes aware that staff have not acted in accordance with the requirements placed on them under the Duty of Candour, the Agency will, in appropriate circumstances, refer the individual(s) concerned to their relevant professional regulator/body, police other relevant body etc.

Appropriate (comprehensive, sequential and complete) written records will be maintained.

In certain cases, incidents occurring will be notified to relevant bodies, e.g. the Police, the Care Quality Commission, etc.

In handling incidents of this kind, the Agency accepts that it must deal sensitively and compassionately with those who may have been affected, including providing all reasonable practical and emotional support necessary to help overcome the physical, psychological and emotional impact of the incident, including:

- being treated with respect, consideration and empathy;
- offered the option of immediate emotional support during the notifications, for example from a family member, a care professional or a trained advocate;

- offered access to assistance with understanding what is being said e.g. via interpretative services, non-verbal communication aids, written information, Braille, etc.;

- providing access to any necessary remedial treatment to minimise or alleviate the harm caused;
- providing the relevant person(s) with information about available impartial advocacy and support services their local Healthwatch and other relevant support groups like Cruse Bereavement Care and Action against Medical Accidents (AvMA) to help them deal with the outcome of incident;
- arranging for care and treatment be delivered by another professional/team or provider as far as reasonably practicable should relevant persons wish.

In continuing its investigation into the incident the Agency will keep the Client informed of any new information which comes to the fore and its conclusions, through a single point of contact identified at the outset.

The outcomes or results of any inquiries and investigations will be provided in writing to the relevant persons, should they wish to receive them. The following Policy/Procedure Statements support the Agency's commitment to Duty of Candour:

a) Accident/Incident Reporting;
b) Complaints;
c) Medicine Administration Errors;
d) Protecting Clients' Rights;
e) Whistleblowing.

References to Legislation and Fundamental Standards	
Health and Social Care Act 2008 (Regulated Activities) Regulations 2014	**Regulation 20**
Fundamental Standards	**Registered persons must be open and transparent with service users about their care and treatment (the duty of candour).**