




 **Review Sheet**

 **Last Reviewed**
12 Sep '24
  **Last Amended**
12 Sep '24
  **Next Planned Review in 12 months, or sooner as required.**

| | |
|--|---|
| Business impact |  <p>These changes require action as soon as possible.</p> <p>HIGH IMPACT</p> |
| Reason for this review | Scheduled review |
| Were changes made? | Yes |
| Summary: | This policy has been reviewed and amended in order to include overall management responsibility of the policy in line with the updated CQC guidance on Supporting documents: provider registration applications. |
| Relevant legislation: | <ul style="list-style-type: none"> • Criminal Justice and Courts Act 2015 • The Care Act 2014 • Equality Act 2010 • The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 • Health and Social Care Act 2008 (Registration and Regulated Activities) (Amendment) Regulations 2015 • Mental Capacity Act 2005 • Mental Capacity Act Code of Practice • Data Protection Act 2018 • The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 • UK GDPR • Health and Care Act 2022 |
| Underpinning knowledge - What have we used to ensure that the policy is current: | <ul style="list-style-type: none"> • Author: Action Against Medical Accidents, (2023), <i>Duty of candour</i>. [Online] Available from: https://www.avma.org.uk/policy-campaigns/duty-of-candour/ [Accessed: 12/9/2024] • Author: Department of Health and Social Care, (2014), <i>Statutory duty of candour for health and adult social care providers</i>. [Online] Available from: https://www.gov.uk/government/consultations/statutory-duty-of-candour-for-health-and-adult-social-care-providers [Accessed: 12/9/2024] • Author: CARE QUALITY COMMISSION (CQC), (2022), <i>Duty of candour: notifiable safety incidents</i>. [Online] Available from: https://www.cqc.org.uk/guidance-providers/all-services/duty-candour-notifiable-safety-incidents [Accessed: 12/9/2024] • Author: Nursing and Midwifery Council, (2022), <i>Guidance on the professional duty of candour</i>. [Online] Available from: https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/ [Accessed: 8/1/2025] • Author: Royal College of Nursing and General Medical Council, (2024), <i>Duty of candour</i>. [Online] Available from: https://www.rcn.org.uk/get-help/rcn-advice/duty-of-candour [Accessed: 12/9/2024] • Author: Care Quality Commission, (2022), <i>Regulation 20: Duty of Candour (Provider Guidance)</i>. [Online] Available from: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#hide7 [Accessed: 12/9/2024] • Author: NHS ENGLAND, (2024), <i>Accessible Information Standard</i>. [Online] Available from: https://www.england.nhs.uk/ourwork/accessibleinfo/ [Accessed: 12/9/2024] |
| Suggested action: | <ul style="list-style-type: none"> • Encourage sharing the policy through the use of the QCS App |

THE BIS SERVICES LIMITED

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Equality Impact Assessment:

QCS have undertaken an equality analysis during the review of this policy. This statement is a written record that demonstrates that we have shown due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations with respect to the characteristics protected by equality law.

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1. Purpose

1.1 To set out the responsibilities of THE BIS SERVICES LIMITED under The Health and Social Care Act 2008 (as amended) and Regulation 20: The Duty of Candour. THE BIS SERVICES LIMITED will act in an open and clear way about Client care and treatment.

1.2 To support THE BIS SERVICES LIMITED in meeting the following Key Lines of Enquiry/Quality Statements (New):

| Key Question | Key Lines of Enquiry | Quality Statements (New) |
|--------------|---|--|
| SAFE | S2: How are risks to people assessed and their safety monitored and managed so they are supported to stay safe and their freedom is respected? | QSS4: Involving people to manage risks QSS5: Safe environments |
| WELL-LED | W1: Is there a clear vision and credible strategy to deliver high-quality care and support, and promote a positive culture that is person-centred, open, inclusive and empowering, which achieves good outcomes for people? | QSW1: Shared direction and culture QSW2: Capable, compassionate and inclusive leaders |

1.3 To meet the legal requirements of the regulated activities that THE BIS SERVICES LIMITED is registered to provide:

- | Criminal Justice and Courts Act 2015
- | The Care Act 2014
- | Equality Act 2010
- | The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- | Health and Social Care Act 2008 (Registration and Regulated Activities) (Amendment) Regulations 2015
- | Mental Capacity Act 2005
- | Mental Capacity Act Code of Practice
- | Data Protection Act 2018
- | The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012
- | UK GDPR
- | Health and Care Act 2022



2. Scope

- 2.1** The following roles may be affected by this policy:
- | All staff
- 2.2** The following Clients may be affected by this policy:
- | Clients
- 2.3** The following stakeholders may be affected by this policy:
- | Family
 - | Advocates
 - | Representatives
 - | Commissioners
 - | External health professionals
 - | Local Authority
 - | NHS



3. Objectives

- 3.1** THE BIS SERVICES LIMITED promotes a culture of being:

- | Open
- | Honest
- | Transparent

Clients are provided with Care that is safe, effective and based on best practice. Where any incidents occur that may have the potential to cause harm, THE BIS SERVICES LIMITED will act in a timely manner, investigating, reflecting, learning and, where appropriate to do so, sharing information to reduce the risk of reoccurrence.

- 3.2** THE BIS SERVICES LIMITED understands there are two types of duty of candour:

- | Statutory duty
- | Professional duty

THE BIS SERVICES LIMITED is regulated under the statutory duty of candour.

However, certain groups of staff at THE BIS SERVICES LIMITED may also fall under the professional duty of candour, including specific roles within the Nursing and Midwifery Council (NMC).



4. Policy

4.1 The Registered Manager, Ekvinder Popat, and Nominated Individual, Natalie Mackenzie, of THE BIS SERVICES LIMITED, have overall management responsibility for this policy and procedure. This is in line with the Policy Management Policy and Procedure at THE BIS SERVICES LIMITED.

4.2 To meet the requirements of the duty of candour, THE BIS SERVICES LIMITED must make public commitments to relevant persons to transparency, openness and fairness in relation to the care, support and treatment of Clients.

4.3 The relevant person must be notified in person as soon as possible, and this will be followed up with a written notification that includes:

- | A factual account of the incident
- | An apology
- | What further enquiries will be taking place
- | Confirmation of when an update will be provided
- | A further notification, including an apology and details of the outcome of any further investigations

4.4 THE BIS SERVICES LIMITED will encourage a culture of openness and transparency by leading by example through its day-to-day actions and communications.

4.5 THE BIS SERVICES LIMITED will support employees at all levels to follow this commitment, ensuring that they are not obstructed to do so.

4.6 THE BIS SERVICES LIMITED will take action to remedy any incident of bullying and/or harassment related to the duty of candour.

4.7 Ekvinder Popat will identify any notifiable safety incidents related to the duty of candour.

CQC Notifications page, a link can be found in the Further Reading section.

4.8 Any incident where an individual has been obstructed in carrying out their duty of candour will be investigated by THE BIS SERVICES LIMITED.



5. Procedure

5.1 Awareness of All Staff

- | All staff must be made aware of their personal responsibility to report incidents, regardless of whether they are covered by the duty of candour
- | Each employee will be given the time to read and understand their roles and responsibilities that relate to the duty of candour at the point of induction
- | Duty of candour will be discussed at one-to-one discussions, supervisions, appraisals and staff meetings
- | Staff will be reminded through these communications that attempts by other staff to prevent them from reporting incidents is bullying and/or harassment, and that they must report this immediately to the most senior member of staff on duty (or if not appropriate, a senior manager within THE BIS SERVICES LIMITED)
- | Staff will be reminded that if they are unsure whether the incident is reportable or not, it must be reported anyway

THE BIS SERVICES LIMITED ensures that an organisational training plan includes Duty of Candour within induction, mandatory and refresher training plans. Additional role-specific training is also provided for those who may have additional roles and responsibilities.

5.2 Reporting

- | All staff must report incidents defined in this policy in written form in a clear, accurate way that becomes a permanent record using the Incident and Accident Reporting Form, even if a verbal report has been made
- | The report must be made to the person on duty and in charge of the service at the time of the incident
- | The person on duty then must formally report it to Ekvinder Popat if they are not the same person, as soon as possible

5.3 Make an Initial Assessment

Ekvinder Popat will:

- | Carry out an initial assessment of whether the report includes details of a notifiable safety incident under the regulation (see section 5.4 for more details). If the conclusion is yes, or borderline, continue with this procedure
- | Inform Natalie Mackenzie or their representative of the incident report, and agree with them who is the most appropriate person to continue the procedure. If Ekvinder Popat takes over the role, they will continue the process using the following procedure
- | If it is considered that the incident is not a notifiable safety incident under regulation 20, follow normal incident reporting procedures

5.4 Notifiable Safety Incidents

The CQC clearly defines a 'notifiable safety incident' as a specific term in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all three of the following criteria:

- | It must have been unintended or unexpected
- | It must have occurred during the provision of a regulated activity
- | In the reasonable opinion of a healthcare professional, it already has, or might, result in death, or severe or moderate harm to the person receiving care (this will vary depending on the type of provider)

If any of these three criteria are not met, it is not a notifiable safety incident but THE BIS SERVICES LIMITED will still follow the overarching duty of candour to be open and transparent.

Further information on Duty of candour: notifiable safety incidents is available on the CQC website. (A link can be found in the Further Reading section.)

Examples of Notifiable Safety Incidents

THE BIS SERVICES LIMITED will use three questions in order to decide if an incident meets the notifiable incident requirements of the duty of candour (Regulation 20).

- | **One:** Did something unintended or unexpected happen during the care or treatment?

- | **Two:** Did it occur during the provision of a regulated activity?
- | **Three:** Has it resulted in death or severe or moderate harm?

The answer to all three questions must be 'yes' in order to meet the reporting threshold.

Examples of notifiable safety incidents (duty of candour) are available on the CQC website. (A link can be found in the Further Reading section.)

5.5 Notifying Relevant External Agencies

As with all incidents, it is of utmost importance that this policy is used alongside the relevant external notification procedures to:

- | Ensure that relevant agencies are notified
- | If an investigation is required, that there is an understanding of roles and responsibilities

5.6 Notifying the Relevant Person:

- | One or more suitable representatives of The BIS Services will deliver (as soon as possible and in person) a notification of the incident to the relevant persons
- | THE BIS SERVICES LIMITED must ensure that the relevant person is given the support they need when receiving the information. Depending on the needs of the individual, this may be the offer of an advocate or interpreter, or other communication aids
- | There must be a written record taken of the notification in person, which is kept securely by the Registered Manager, along with any other notes that are taken

The Notification to the Relevant Person Must Include:

- | An accurate account of the incident
- | An apology that the incident occurred. An apology is not an admission of liability, but an apology for the harm caused, regardless of fault, supports the duty of candour requirements
- | An offer to the relevant persons of sources of support and information which will assist them, where appropriate. This may include alternative support from within THE BIS SERVICES LIMITED and external resources, such as advocacy and information services
- | Details of next steps, including timings

5.7 Written Notification

As soon as possible after the notification in person, a written notification will be sent or given to the relevant person containing the same information as above, plus:

- | The results of any enquiries made since the notification in person
- | Any further timescales

5.8 Further Notifications to the Relevant Person(s)

- | The results of any further enquiries and investigations must also be given or sent in writing to the relevant person if they wish to receive them

5.9 Registered Manager's Enquiries and Investigation

- | Ekvinder Popat will assess the information they will need to carry out an investigation, taking statements and gathering information needed
- | Having gathered all the evidence, an investigation must take place
- | All information and evaluation of the information will be recorded and kept securely in line with data protection legislation
- | The purposes of the investigation are to establish if the incident took place, define its nature, gather facts about the processes around the incident, and identify causes where possible

5.10 Final Statement to the Relevant Person(s)

- | Prepare a statement to be given to the relevant person and representative stating the outcome of the investigation, remembering that duty of candour focuses on the transparency and openness of the organisation when such events occur
- | Include any lessons learned and changes made to the service because of the incident
- | The final statement will include a more specific apology as the causes of the incident will now be established

5.11 Correspondence with the Relevant Person

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- | Where for any reason, the relevant person cannot be contacted, or after contact declines to communicate with THE BIS SERVICES LIMITED, a written record of all attempts to contact them must be kept
- | All correspondence with the relevant persons must be recorded and kept securely
- | All correspondence should be written jargon free and where the need is identified, support from an advocate will be offered to ensure the content is accessible to the individual receiving it
- | Reasonable support must be provided to the relevant person throughout the process

5.12 Breach of Candour by a Professionally Registered Person

- | If a breach of candour is found to have occurred following investigation, and that this breach was by a professionally registered person, then that person will be reported to their professional registration body for further consideration
- | The same action will be taken if, during the investigation, it is found that a professionally registered person had obstructed another person in their professional duty of candour

5.13 Reporting a Possible Breach of Candour

- | If any individual believes that a breach of candour has taken place, they must report it to Ekvinder Popat
- | If an individual has been stopped or hindered in their duty of candour, they must report it to Ekvinder Popat
- | Ekvinder Popat will conduct an investigation into the allegations and will report the findings to The BIS Services for action if appropriate
- | If the allegation concerns Ekvinder Popat, the individual must report the matter to The BIS Services directly, who will carry out the investigation and take any action which may be required
- | If the allegation concerns the actions of The BIS Services, the individual must inform The BIS Services and if action is not seen to be taken, the matter must be reported to the Care Quality Commission

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6. Definitions

6.1 Notifiable Safety Incident

- | Regulation 20 (9) in relation to any other provider other than a Health Service Body: In relation to any other registered person, "notifiable safety incident" means any unintended or unexpected incident that occurred in respect of a Client during the provision of a regulated activity that, in the reasonable opinion of a health care professional, appears to have resulted in:
 - | The death of the Client, where the death relates directly to the incident rather than to the natural course of the Client's illness or underlying condition
 - | An impairment of the sensory, motor or intellectual functions of the Client which has lasted, or is likely to last, for a continuous period of at least 28 days
 - | Changes to the structure of the Client's body
 - | The Client experiencing prolonged pain or prolonged psychological harm
 - | The shortening of the life expectancy of the Client

6.2 Relevant Persons

- | In Regulation 20, "relevant person" means the person using the service or, in the following circumstances, a person lawfully acting on their behalf:
 - | When the person using the service dies
 - | Where the person using a service is under 16 and not competent to make a decision in relation to their care or treatment, or
 - | Where the person using the service is 16 or over and lacks capacity to make decisions(CQC Provider Guidance)

6.3 Candour

- | Any person who uses the service harmed by the provision of a service provider is informed of the fact and an appropriate remedy offered, regardless of whether a complaint has been made or a question asked about it
(CQC Duty of Candour Guidance)

6.4 Transparency

- | Allowing information about the truth about performance and outcomes to be shared with staff, people who use the service, the public and regulators

6.5 Openness

- | Enabling concerns and complaints to be raised freely without fear and questions asked to be answered
(CQC Definition)

6.6 Reasonable Support

- | 'Reasonable support' will vary with every situation, but could include, for example:
 - | Environmental adjustments for someone who has a physical disability
 - | An interpreter for someone who does not speak English well
 - | Information in accessible formats
 - | Signposting to mental health services
 - | The support of an advocate
 - | Drawing their attention to other sources of independent help and advice such as AvMA (Action against Medical Accidents) or Cruse Bereavement Care(CQC Definition)

6.7 Definitions of Harm - Common to all types of service

- | **Moderate Harm:** Harm that requires a moderate increase in treatment, including re-admission, prolonging of care, admission to hospital, referral to hospital as an outpatient, cancelling of treatment that is otherwise needed, or transfer to another specialist facility or treatment area
Moderate harm also includes significant (but not permanent) harm
- | **Severe Harm:** 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 Client's illness or underlying condition

- | **Moderate Increase in Treatment:** 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)
- | **Prolonged Pain:** Pain which a Client has experienced, or is likely to experience, for a continuous period of at least 28 days
- | **Prolonged Psychological Harm:** Psychological harm which a Client has experienced, or is likely to experience, for a continuous period of at least 28 days



Key Facts - Professionals

Professionals providing this service should be aware of the following:

- | THE BIS SERVICES LIMITED has a duty to be transparent and open about the Client's care, support and treatment
- | If things go wrong and a notifiable safety incident occurs, the relevant person needs to be notified in person as soon as possible and this must be followed up by a written notification. Both must include the facts about what has happened, an apology, what the next steps are and timescales
- | It is everybody's responsibility to report incidents. Staff will report incidents on the appropriate form to the person in charge
- | Staff will not be stopped from reporting incidents. If staff are prevented or discouraged, this will be investigated
- | THE BIS SERVICES LIMITED will support staff if they need to be involved in a notifiable incident
- | Other staff may be asked to support the relevant person when they receive a notification if they are the best person to do this
- | THE BIS SERVICES LIMITED will use three questions in order to decide if an incident meets the notifiable incident requirements of the duty of candour (Regulation 20)



Key Facts - People affected by the service

People affected by this service should be aware of the following:

- | The law says that THE BIS SERVICES LIMITED will tell you if things go wrong with your care, support or treatment, and you are hurt. The provider must tell you what has happened
- | When THE BIS SERVICES LIMITED tells you, they need to tell you certain things. These are the facts of what happened, what will happen next, and they will also give you an apology
- | THE BIS SERVICES LIMITED will offer you support to understand this at the time they tell you, and throughout the process
- | You will receive a letter which may be given or sent to you in the post (which tells you the same information) shortly after you are told. It will also give you any further dates or information on what has happened since
- | As the provider of the service we have assessed your information needs. We will make sure you have the right help for you to understand the information you receive
- | You may get further information before the end of the process. It is up to you whether you want to have that information. THE BIS SERVICES LIMITED will respect what you want to do and will make a note of it for their records
- | When the process has finished, THE BIS SERVICES LIMITED will tell you what happened, and what they are going to do to make it right



Further Reading

As well as the information in the 'underpinning knowledge' section of the review sheet we recommend that you add to your understanding in this policy area by considering the following materials:

CQC. Examples of notifiable safety incidents (duty of candour):

<https://www.cqc.org.uk/guidance-providers/all-services/duty-candour-examples-notifiable-safety-incidents>

CQC. Notifications:

https://www.cqc.org.uk/guidance-regulation/providers/notifications?field_keywords_tid_1=&page=2

AvMA - The Duty of Candour - The legal duty to be open and honest when things go wrong - What it means for patients and their families:

<https://www.avma.org.uk/wp-content/uploads/Duty-of-candour.pdf>

AvMA - Action against Medical Accidents:

<https://www.avma.org.uk/>

Department of Health - Duty of Candour, Our Consultation - Easy Read:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/295624/Duty_of_



Outstanding Practice

To be 'outstanding' in this policy area you could provide evidence that:

- 1 Transparency is embedded in the culture at THE BIS SERVICES LIMITED and the same procedures to notify relevant persons are used, even when the threshold for Regulation 20 is not met in regard to the level of harm caused
- 1 Improvements and changes made due to Notifiable Safety Incidents are shared with relevant persons
- 1 The wide understanding of the policy is enabled by proactive use of the QCS App



Forms

The following forms are included as part of this policy:

| Title of form | When would the form be used? | Created by |
|---|--|------------|
| Initial Notification to Relevant Persons Regarding Duty of Candour - AR38 | When a notifiable safety incident occurs and triggers Regulation 20 Duty of Candour. | QCS |

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Suggested template initial notification letter. Transfer to your own letterhead, format and edit as required where indicated. PLEASE NOTE: If the notification is addressed to a relevant person who is not the service user involved as per the policy, please edit accordingly.

[Date]

Dear [the relevant person],

Notification under the Duty of Candour Regulations

I am writing to you to inform you of an incident which has occurred involving you/, [insert Client's name]. The details of the incident, as they are known at the time of writing this letter, are:

Date: _____

Time: _____

Location: _____

Nature of the incident: [describe the incident, not naming persons involved (other than the Client) if possible, taking into account the definitions of an "incident" as set out in the policy section of this policy and procedure.]

I am sorry that this has happened to [you/Client's name]. I have begun the process of conducting an investigation into the incident.

As part of the investigation, I expect to interview:

- [List people by post or function, avoiding names if possible]

I will also be gathering the following information:

- [List the information you are planning to gather and review only if relevant]

I will be making arrangements to support you during the investigation, and also in response to the effects this may have had on you. [Edit as appropriate, and detail the support to be offered]

I will give you further information by [date] and will inform you if this date changes. This may only be interim information if I have not completed my investigations, in which case I will give you a predicted date for the end of the investigation.

If these target dates cannot be met because of issues which I am currently unaware of, I will contact you to let you know reasons for the delay, the progress to date, and revised dates.

Yours sincerely,

Registered Manager

An edited version of this letter can be used to make the final notification, by editing out the references to a pending investigation and support, substituting the outcome of the investigation, and firming up on the apology in line with those conclusions.