

Registration under the Health and Social Care Act
2008

Statutory notifications

Guidance for registered providers
and managers of:

- independent healthcare
- adult social care
- primary dental care
- private ambulances

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Contents

Summary	3
What must be notified and how to submit notifications	3
1. Which regulations say what must be notified to CQC?	3
2. How do I submit a notification?	3
3. Who should fill in and submit notification forms?	5
4. What if I need to submit more information about a notified event later on?	5
5. Why do I have to use ID codes instead of people's names when I submit notifications?	5
6. Why does CQC ask about people's ethnicity, religion and so on?	6
7. Do I have to notify CQC about outbreaks of infection?	6
8. Do I have to notify CQC about medicines errors?	7
Using CQC's notification forms	7
9. How do I fill in and edit CQC's 'protected' Word document forms?	8
10. How do I make changes to my statement of purpose (Regulation 12)?	8
11. How do I notify CQC about absences of registered persons (and returns from absence) of 28 days or more? (Regulation 14)	8
12. How do I notify you about changes to my registration details? (Regulation 15)	9
13. Death of a person who uses the service (Regulation 16)	10
14. Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983 (Regulation 17)	10
15. Notifications about 'other incidents' (Regulation 18)	11
16. 'Duty of Candour' (Regulation 20 of the Regulated Activities Regulations 2014)	12
Tools for the job	12

Summary

If you are a registered provider or a registered manager of:

- independent healthcare
- adult social care
- primary dental care, or
- private ambulance services

you are required to notify CQC of certain incidents, events or changes to your service.

This guidance tells you what you must notify CQC about, the forms you must use, how to submit the information to us, and what we do with the information.

What must be notified and how to submit notifications

1. Which regulations say what must be notified to CQC?

Regulations 12, 14, 15, 16, 17, 18, 20, 21 and 22 of the Care Quality Commission (Registration) Regulations 2009 make requirements that the details of certain incidents, events and changes that affect a service, or the people using it, are notified to CQC.

Please note that Regulations 12, 16, 17 and 18 were amended in 2012 and the detail of some requirements have changed.

You can read the up-to-date regulations and fundamental standards on our [website](#). They are also in other publications and on other websites, but they may not be completely up to date.

It is an offence not to notify CQC when a relevant incident, event or change has occurred.

NHS bodies (only) can submit some notifications through the NHS Commissioning Body's National Reporting and Learning System (NRLS – the system run previously by the National Patient Safety Agency); this does not apply to providers of adult social care, independent healthcare, primary dental care and private ambulance services. You can read a summary of the notifications requirements in sections 11-16 below.

2. How do I submit a notification?

Registered persons must use the forms supplied by CQC to submit notifications. We will be introducing electronic online

forms to enable providers to submit notifications in due course, and guidance about how to use them.

Until the online forms become available, you must download, fill in and submit the notification forms in Microsoft Word document format, which you can find on our website.

You don't need to have Microsoft Word installed on your computer to open and use the forms; you can do so using 'Open Office' – a free programme that you can download from the internet at: www.openoffice.org.

When the online system becomes available you will be able to fill in and submit notifications online by logging into an online account using a username and password, which we will provide.

The online system automatically assigns a reference number to each notification. You will be able to see a history of the notifications you have submitted.

There are separate arrangements for notifications about deaths and unauthorised absences of people who are detained, or liable to be detained, under the Mental Health Act. This is because they are part of our Mental Health Act monitoring functions. You can download these notification forms and get information about how to submit them from our website.

When using Word forms, you should assign your own reference number or code in the space provided at the top of each form. You should keep a record of this code so that if we need more information about the incident, event, or change you have notified us about you can easily look it up.

When complete, you submit an online form by clicking the appropriate button. To submit a Word form, you attach it to an email and send to: HSCA_notifications@cqc.org.uk

If you don't have access to the internet, you should contact us to ask for a hard copy of each form so that you can make copies and have them ready for use when needed. Printed forms should be filled in by hand and sent to:

Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

The forms make it clear which information must be submitted. They also ask for additional information that helps us to

understand what has happened and how you have responded to it.

If registered persons submit this additional information, it will often mean that we don't have to contact or visit them to gather more information.

3. Who should fill in and submit notification forms?

The regulations say that the 'registered person' must submit notifications. This will often be the registered manager, but you can delegate this task to appropriate members of staff.

You need to ensure that your delegation arrangements clearly show which members of staff are responsible for submitting notifications. These, together with your policies and procedures and staff training arrangements, must ensure that CQC is told about notifiable events properly and within the required timescales.

In all cases, we need to know the name of the person who submits a notification and who we should contact for more information. There is space in the forms for this.

It is the registered person's responsibility to ensure that notifications are made, and they will be committing an offence if they fail to do so. Any arrangements for delegation of this task must therefore be very clear.

4. What if I need to submit more information about a notified event later on?

If you need to tell us more about an event or incident after you have submitted a notification, for example about a safeguarding alert, you can do so to the notifications email or postal address above.

Always quote the reference number that you assigned to the original notification when you contact us to discuss the notified event or to give us more information.

Some notification forms are designed to enable you to submit follow-on information to previous notifications. In this case, please quote the reference number for the original notification in the space provided for it. This helps us to quickly link the new information to the original notification.

5. Why do I have to use ID codes

If you submitted a notification that included confidential information, such as a person's name or any other information

instead of people's names when I submit notifications?

that could identify them as an individual, it may contravene the Data Protection Act 1998.

The Data Protection Act makes important requirements about how information about people is stored, 'processed' and shared. It is important that this information is only shared when necessary, and under appropriate security arrangements. We therefore ask registered persons to use a unique identifier or code rather than a name when giving information about a person in a notification.

You can allocate a code to each person who uses your service, and use this code in statutory notifications. You must keep information about who these codes refer to safely and securely, in case we need to know more about a notified event. It is up to you to decide the format of the codes.

Even where you use codes, they must not easily identify the person, such as by using their room number or date of birth.

6. Why does CQC ask about people's ethnicity, religion and so on?

It is important that health and social care services take account of people's diverse needs when carrying on regulated activities, and also that they monitor how well they are meeting them.

CQC has a statutory duty as a public body to monitor and report on how well both individual providers and the health and social care sector as a whole are promoting equality and meeting people's diverse needs.

We ask you to tell us about protected characteristics in relevant notification forms using the 'equality strands' that are widely used across government and the economy. You should collect this information when accepting or admitting people under Outcomes 1 and 4 of the Guidance about compliance ('respecting and involving people who use services' and 'care and welfare of people who use services'), so it should be readily available.

7. Do I have to notify CQC about outbreaks of infection?

No. But you should notify Public Health England (PHE), previously called the Health Protection Agency, about certain infection outbreaks and incidents.

PHE and the Department of Health have published The Health Protection Legislation (England) Guidance 2010, which explains what needs to be notified to PHE. You should read it

to understand what needs to be notified, and how to comply with the regulations.

The diseases and causes that must be notified are listed in schedules 1 and 2 of the regulations. Registered medical practitioners are required to report the diseases listed in schedule 1. Diagnostic laboratories testing human samples are required to report the 'causative agents' listed in schedule 2.

The Health and Social Care Act 2008 code of practice for the prevention and control of infections requires that NHS providers report cases and outbreaks of certain infections. This includes cases and outbreaks in the adult social care activities they carry on. These infections are:

- *Clostridium difficile*.
- Blood stream infections caused by meticillin resistant staphylococcus aureus (MRSA) and glycopeptide resistant enterococci (GRE).
- Surgical site infections (SSI) following orthopaedic surgery.

Certain infections or conditions are also notifiable to the Office of National Statistics by law. These notifications are submitted by any doctor in clinical practice.

Other notifications about outbreaks and relevant individual infections are reported by doctors, diagnostic laboratories and relevant NHS trust staff.

8. Do I have to notify CQC about medicines errors?

There is no requirement to notify CQC about medicines errors, but a notification would be required if the cause or effect of a medicine error met the criteria to notify one of the following:

- A death
- An injury
- Abuse, or an allegation of abuse
- An incident reported to or investigated by the police

Where relevant, you should make it clear that a medicine error was a known or possible cause or effect of these incidents or events being notified.

Using CQC's notification forms

9. How do I fill in and edit CQC's 'protected' Word document forms?

When filling the forms in on a computer, you can move from field to field by pressing the 'page up', 'page down', 'tab' or arrow keys, or by using a mouse.

Enter text in the normal way using a keyboard. You can copy and paste normally, but spelling and grammar checking, bullet points and numbered lists do not work in protected forms. If you want to use these functions you can type text into a normal word document and then copy and paste it into relevant fields of the notification form.

You can tick boxes by using the space bar when the boxes are highlighted, or by left clicking on them with a mouse.

10. How do I make changes to my statement of purpose (Regulation 12)?

You must notify us about changes to your statement of purpose within 28 days.

Fill in or amend the relevant part(s) of our standard statement of purpose template (or amend your own alternative document), then fill in the change of statement of purpose notification form, attach them to an email and send to us.

There is separate guidance on completing and submitting statements of purpose.

These notifications are always classed as 'significant'.

11. How do I notify CQC about absences of registered persons (and returns from absence) of 28 days or more? (Regulation 14)

A registered person must use our standard form to notify us about relevant absences (and arrangements for managing the activity during the absence) and to tell us that they have returned from a notified absence.

(For NHS providers, these notifications only apply to people registered as managers in relation to adult social care activities.)

Timescales for notifications relating to Regulation 14:

- Notifications about planned absences of 28 days or more must be submitted 28 days before they begin.
 - You can agree shorter timescales with us where appropriate but you must contact us to discuss this when needed.
 - Where an absence is caused by an emergency, you must
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submit the notification within five working days of the start of the absence.

- Where a required notification of absence has not already been submitted, you must send it to us immediately.
- You must notify us of returns to work from an absence within seven days.

Where an absence is likely to be lengthy but you are not sure how long it will last, you can propose a date by when a new manager will be appointed and will apply for registration if the absent person has not returned to work (there is a space on the form for this). We will review the proposed date and agree it if it is appropriate or discuss the matter with the provider if it is not.

These notifications are always classed as 'significant'.

12. How do I notify you about changes to my registration details?
(Regulation 15)

The standard form 'Changes affecting a provider or manager' allows you to make notifications about the variety of changes covered by Regulation 15.

You must submit a notification of these changes as soon as reasonably practicable and in advance of the change unless this is not possible.

You can also use this form to tell us about other important changes that are not covered by the notifications regulations, such as:

- Letting us know about a change to the email address that we should use to send you statutory notices if you have previously told us that you are willing to receive them by email.
- Changes to your main contact telephone number.

NHS providers can also use this form to tell us about changes of their chief executive.

You should always complete Section 1 of the form. Then use the following sections (as needed) to notify us about:

Section	Change
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2	Changes of provider for an activity
3	Changes of registered manager for an activity
4	Changes to a registered individual's name
5	Changes to the membership of a partnership
6	Changes to an organisation's name or address
7	The appointment of a new nominated individual
8	Changes to an organisation's officers or directors (NHS bodies should use this section to tell us about new chief executives)
9	Changes of main contact email address and telephone number
10	The appointment of a trustee in bankruptcy, receiver, or liquidator
11	The sequestration of a registered person's estate

Please note: if any of the above changes mean that the content of your statement of purpose will also have to change, you must make the relevant amendments, fill in a notification form for this change, and send us a copy of the new statement of purpose with the notification form. Please see our separate guidance about statements of purpose.

You can use section 12 to clarify anything, or to give us any additional relevant information.

These notifications can be either significant or routine.

13. Death of a person who uses the service (Regulation 16)

These notifications must be submitted without delay.

'Without delay' is the timescale requirement for a number of notifications. It means exactly what it says – that providers should submit their notification as quickly as possible after the event has happened.

There are sections on the form to enable you to tell us about the circumstances of the death (as required by the regulation).

These notifications can be either significant or routine.

14. Deaths and unauthorised absences of people who are

We handle these notifications separately from other notifications because they inform our statutory Mental Health Act monitoring duties as well as our functions under the Health and Social Care Act 2008. You can get more

detained or liable to be detained under the Mental Health Act 1983 (Regulation 17)

information about this on our website [Mental Health Act notifications pages](#).

These notifications must be submitted without delay.

15. Notifications about 'other incidents'
(Regulation 18)

The law says that registered persons must notify us without delay if a variety of 'other incidents' take place while an activity is being delivered or as a consequence of an activity being delivered. These incidents are:

Serious injuries

Registered persons must notify us whenever any of the injuries occur that are shown on our form.

Deprivation of liberty applications and their outcomes

You must notify us about any applications you make to deprive a person of their liberty under the Mental Capacity Act 2005 and about the outcome of those applications. You can do this using one standard form as soon as you know the outcome of the application.

Abuse and allegations of abuse

You must notify CQC about abuse or alleged abuse involving a person(s) using your service. This includes where the person(s) is either the victim(s) or the abuser(s), or both.

When you notify us about abuse or alleged abuse, you must also alert the relevant local safeguarding authority for children or adults, and the police where a crime has been or may have been committed.

Incidents reported to, or investigated by, the police

You must notify us about any incident related to your carrying on of a regulated activity that is reported to, or investigated by, the police.

Events that stop, or may stop, the registered person from running the service safely and properly

You must notify us about any relevant infrastructure, equipment, premises or other problems that prevent, or are likely to prevent, you from carrying on the regulated activity safely and in accordance with the fundamental standards.

The admission of a child or young person under 18 to an

adult psychiatric ward or unit

Registered persons who provide psychiatric units for adults must notify CQC if they admit a child or young person aged under 18 to such a location if that placement has lasted for a continuous period longer than 48 hours.

16. **‘Duty of Candour’** (Regulation 20 of the Regulated Activities Regulations 2014)

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other ‘relevant persons’ (people acting lawfully on behalf of them) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment – that they inform service users or relevant persons of the incident, that they provide them with reasonable support, truthful information and an apology when things go wrong.

If a notifiable safety incident has occurred, you should record what action you have taken in relation to this regulation in the applicable notification form:

- **Death of a person who uses the service**
 - **Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983**
 - **Serious injuries to a person who uses the service**
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Tools for the job

[Regulations and Fundamental Standards](#)

[Notifications for Non-NHS Providers](#)
