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
- primary medical services

July 2012
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Summary

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

• independent healthcare
• adult social care
• primary dental care
• private dental care, or
• primary medical 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.

These regulations were amended in 2012 and the amendments came into force on 18 June 2012. You should read the regulations and relevant outcomes in the Guidance about compliance: Essential standards of quality and safety so that you understand what must be notified to CQC. Please note that some of the regulations quoted in the essential standards have been amended.

You can also find them in other publications and at other websites, but they may not be completely up to date. If you use the search function on our website www.cqc.org.uk you can find a continuously updated version of the regulations.

We have provided a summary of the notifications requirements in sections 10-16 below.
The changes from 18 June 2012 are summarised below:

- Notifications submitted in relation to regulations 14-18, 21 and 22 must now be made using the forms supplied by CQC. You can find them on our website.

- Deaths must now be notified where they were, or may have resulted from the carrying on of a regulated activity, rather than as a consequence of it.

- The criteria for primary medical service providers to notify CQC of a death are the same as those applied to NHS bodies, with the additional criterion that the death must have occurred within two weeks of regulated activity having been provided.

- Primary medical services providers must submit all notifications directly to CQC; they cannot submit notifications to us through the former NPSA National Reporting and Learning System (NRLS).

- Deaths of people detained or liable to be detained under the Mental Health Act must now only be notified where the setting is secure.

- Notifications about an application to deprive a person of their liberty and about the outcome of the application (together with relevant details) are now made together in the same notification, when the outcome is known.

The regulations say that the ‘registered person’ must submit notifications. This can be either the provider or a registered manager. In practice, some larger providers need to 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.

Your delegation arrangements, together with other 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. How do I submit a notification?

You must use the Microsoft Word forms that we provide on our website to submit notifications. We will introduce electronic online webforms to submit notifications directly from our website in the future.

Until the online forms are available, you must download the Word forms from the website, fill them in and submit them by email. There is more information about submitting notifications 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.

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.

You should assign your own reference number or code in the space provided at the top of each form and keep a record of this code. If we need more information about the incident, event or change, you will be able to look it up more easily.

When you have filled in a notification form (except those about unauthorised absences and deaths of people detained under the Mental Health Act) you should send it as an attachment to an email to:

HSCA_notifications@cqc.org.uk

The forms make it clear which information you must submit. They also ask for additional information that helps us to understand what has happened and how your service has responded to it.

By submitting this additional information it will often mean that we don’t have to contact or visit you to gather more information.

Until the new electronic online forms become available, you should email your notifications to us wherever possible.
If you don’t have access to the internet, you can ask us for a hard copy of each form and make extra copies ready for use when needed. Please fill in printed forms by hand and post to:

Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

5. 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.

6. Why do I have to use ID codes instead of people’s names when I submit notifications?

If you submitted a notification that included confidential information such as a person’s name or any other information that could identify them as an individual, it would 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, 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 the 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.
7. 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.

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

No. You should notify the Health Protection Agency (HPA) about certain infection outbreaks and incidents.

The Health Protection Agency and Department of Health have published The Health Protection Legislation (England) Guidance 2010, which explains what needs to be notified to the HPA. Registered persons should read it to understand what needs to be notified to the HPA 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.

The HPA will liaise with CQC over outbreaks and incidents when this is needed.

9. Where can I find out more about the changes, events and incidents that have to be notified to CQC?

See the relevant outcome sections in the Essential standards of quality and safety, which include detailed information about notifications requirements. Please note that some of the regulations have been amended since the Essential standards were published.

You can see a continuously updated version of the regulations by using the search tool on our website www.cqc.org.uk.

Using the CQC notification forms

10. 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.

11. 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’.

12. 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 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’.

13. 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 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 chief executive.

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

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

**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.
14. 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.

15. Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983 (Regulation 17)

We handle these notifications separately from other notifications because they inform our statutory Mental Health Act monitoring duties. You can get more information about this on our website on the Mental Health Act notifications pages.

These notifications must be submitted **without delay**.

16. 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 listed in the *Essential standards of quality and safety* and shown on our form occur.

These notifications are always classed as ‘significant’.

**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.

These notifications are always ‘routine’.

**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.
There is more information about what must be notified in the *Essential standards of quality and safety*.

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.

These notifications are always ‘significant’.

**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.

These notifications can be either ‘significant’ or ‘routine’.

**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 Essential standards of quality and safety.

These notifications are always ‘significant’.