

Registration under the Health and Social Care Act 2008

Statutory Notifications

Guidance for registered providers and
managers of NHS GP and other primary
medical services

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Summary

Registered providers and managers of NHS GP and other primary medical services are required to notify CQC about certain incidents, events and changes in their service. This guidance tells you how to submit this information to CQC, and what we do with it.

What you must notify CQC about

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.

The regulations and relevant outcomes are included in the [Essential standards quality and safety](#), but please note that Regulations 12, 16, 17 and 18 were amended in 2012.

You can read the up to date regulations on our website. You can also find them in other publications and at 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.

Please note that only NHS bodies can submit notifications through NHS England's National Reporting and Learning System (NRLS – the system run previously by the National Patient Safety Agency). GP and other primary medical services must submit all notifications directly to CQC.

You can read a summary of the notifications requirements in sections 11 - 16 of this guidance.

Submitting notifications

2. Who should fill in and submit notification forms?

The regulations say that the 'registered person' must submit notifications. Registered persons are the organisations, partnerships or individuals registered to provide regulated activities under the Health and Social Care Act 2008, and any registered managers they employ. Notifications are often submitted by registered managers, but you can delegate this task to other appropriate members of staff.

You need to make sure that your delegation arrangements clearly show which members of staff are responsible for submitting notifications. 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 your responsibility to ensure that notifications are made, and you will be committing an offence if you fail to do so. Any arrangements for delegation of this task must therefore be very clear.

3. How do I submit a notification?

You must use the forms supplied by CQC to submit notifications. We are introducing electronic online forms to submit notifications directly from our website.

However, until they become available you must download, fill in and submit the forms as Microsoft Word documents, which are on our website. There is more information about submitting notifications using CQC's Word forms on our website.

Microsoft Word forms

If you are using a Word version of the form, you should assign your own reference number or code to the space provided at the top of the first page. You should keep a record of this code so that if we need more information about the incident, event, or change, you can look it up more easily.

Complete all the relevant fields and attach the document to an email to:

HSCA_notifications@cqc.org.uk

The online forms will be available to providers and managers of NHS GP and other primary medical services during the spring of 2013. We will email providers and managers to tell you how to use them when they are available.

You will be able to submit notifications online by logging on to your online account with the username and password we will give you.

The online system automatically assigns a reference number to each notification. You can also see a history of the notifications you have submitted to us.

For both Word and online forms, you must complete all relevant fields. 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 may mean that we don't have to contact or visit you to gather more information.

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 by sending an email to the notifications email address shown above.

Always quote the reference number that was assigned to the original notification when you 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 original reference number in the space provided. This helps us to quickly link the new information to the original notification.

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

If you include confidential information such as a person's name or other information that could identify them as an individual in a notification, you could be acting in breach of the Data Protection Act and other duties in relation to confidentiality.

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, and only with appropriate people. You must therefore use unique identifiers or codes, rather than names, 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.

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 (formerly the Health Protection Agency (HPA)) about certain infection outbreaks and incidents.

The Department of Health 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.

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

8. 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 Guidance about compliance: 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 standards were published.

The following pages refer to the changes that affected death notifications from NHS GP and other primary medical services.

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

Using CQC's notification forms

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

The Microsoft Word documents are 'protected' forms. This means that when you fill them 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 fill in and edit CQC's electronic webforms?

Our online forms are easy to use. When you log in to your account to submit a notification, the first page you see has all the guidance and information you need, and tells you how long it will take.

The forms make sure you provide all the information required and that your answers are in the correct format.

There are links throughout the forms to provide help to answer the questions. If you click on one of these links a 'help panel' will appear on the right-hand side of the page.

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.

There are webform and protected Word document versions of the notification form, and a three-part Word template for the statement of purpose (SoP) itself.

Firstly, fill in or amend the relevant part(s) of our standard statement of purpose template (or amend your own document). Then, either log on to your online account and submit a change of SoP form, or fill in and send us a Word version of the change of statement of purpose notification form.

If using the Word notification form, attach the SoP and notification forms to an email and send it to us at HSCA_Notifications@cqc.org.uk.

When the online forms are available, you will be able to upload the new version of your SoP through your account.

When you apply online to make a change that will affect your SoP, you will be prompted to upload a new version of the statement in the form you are completing. There will also be a form to allow you to update your SoP when not submitting an application.

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

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

This requirement only applies to registered providers that are individuals (not partners, partnerships or organisations) and registered managers.

You must use the Regulation 14 (absences) online or Word form to notify us about relevant absences (and arrangements for managing the activity during the absence). There are also forms for you to tell us that you have returned from a notified absence.

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.

13. How do I notify CQC about changes to my registration details?

(Regulation 15)

You must use our standard Regulation 15 (changes) Word form or the relevant online form to notify us about the certain changes affecting your service.

You must submit changes notifications ‘as soon as reasonably practicable’, and in advance of the change unless this is not possible.

You can also use the Word form and an online form to tell us about other important changes that are not covered by the notifications regulations, such as a change to your main contact telephone number.

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

Section	Change
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 the notification form for this change, and send us a copy of the new statement of purpose. Please see our separate guidance about statements of purpose.

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

Open the online forms by logging on to your account. You will only have access to the forms that are relevant to your service

(for example, a provider that is an organisation would not see links to forms for making changes to a partnership).

There will also be guidance on each form, which advises you on how and when to fill it in, and about any related applications you may have to make.

You will also be able to submit online forms to tell us about other important changes that are not covered by the notifications regulations, for example to your main contact telephone number.

14. How do I notify CQC about the 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 you should submit relevant notifications as quickly as possible after the event has happened.

Providers and managers of NHS GP and other primary medical services do not need to notify CQC about **every** death of a person using the service.

However, deaths must be notified where:

- The death occurred while regulated activity was *actually being provided*. For example, while a patient was actually in consultation with their GP, while at their health centre or surgery, or during a home visit.

OR

- The death occurred within two weeks of regulated activity being provided (as above)

AND

The death was or may have been the result of the regulated activity or how it was provided

AND

In your reasonable opinion, the death could not be attributed to the course which the illness or medical condition would naturally have taken if the deceased had been receiving appropriate care and treatment.

There are sections on both the Word and online forms to tell us about the circumstances of the death (as required by the regulation).

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

These notifications do not need to be submitted if you are solely a primary medical service provider.

Providers and managers who are also registered in respect of other relevant service types can get more information from the *Guidance about compliance: Essential standards of quality and safety* and the notifications guidance for the relevant kind of service.

16. How do I submit notifications about 'other incidents'?
(Regulation 18)

The law says that you must notify us without delay if certain specific incidents take place *while an activity is actually being provided*, or were *a consequence of its being provided*. These incidents are:

Serious injuries

You must notify us whenever any of the injuries and related circumstances described in the Essential standards of quality and safety (and shown on our notification form) occur.

Deprivation of liberty applications and their outcomes

These notifications do not need to be submitted if you are solely a primary medical services provider. Providers and managers who are also registered in respect of other relevant service types can get more information from the *Guidance about compliance: Essential standards of quality and safety* and the notifications guidance for the relevant kind of service.

Abuse and allegations of abuse

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

The definition of a vulnerable adult is that used in the Department of Health's guidance 'No Secrets', which defines them as a person: "*who is or may be in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation*". The circumstances of other kinds of domestic abuse do not need to be notified to CQC.

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

When you notify us about abuse or alleged abuse of children or vulnerable adults, you must also alert the relevant local safeguarding authority, 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 carrying on your service 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 *Guidance about compliance: Essential standards of quality and safety*.
