Care Quality Commission

Registration under the Health and Social Care Act 2008

Statutory notifications

Guidance for registered providers and managers of NHS organisations

July 2012

Contents

Summary

NHS providers and their registered managers are required by law to notify CQC about certain incidents, events and changes to their service. This guidance tells you what you must notify CQC about, the forms you must use, the notifications you have to submit to the National Reporting and Learning System, and how we process notifications.

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.

The regulations also say that NHS bodies can submit certain of these notifications to the National Patient Safety Agency (NPSA – see more below). These notifications are then forwarded to CQC under an information sharing agreement.

The NPSA has now been closed, but the National Reporting and Learning System (NRLS) continues to be provided by Imperial College NHS Trust, under contract to the NHS Commissioning Board.

The regulations concerning notifications were amended in 2012, with the amendments coming 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, but please note that some of the regulations quoted in the essential standards have now been amended.

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

You can see a summary of the notifications requirements in sections 15 to 20 of this guidance.

2. What amendments were made to the regulations in June 2012?

The changes from 18 June 2012 are summarised below:

- Notifications submitted in relation to regulations 14-18, 21 and 22 and submitted directly to CQC 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 a death to be notified by primary medical service providers 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 service providers must submit all notifications directly to CQC; they cannot submit notifications to us through the former NPSA National Reporting and Learning System (NRLS).

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

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

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3. Who should fill in and submit notification forms?

The regulations say that the 'registered person' (registered provider or registered manager) must submit notifications; this applies to the NHS body as a whole. In practice, you will normally need to create delegation arrangements to meet this obligation.

You need to ensure that your delegation arrangements clearly show which staff are responsible for submitting notifications.

Schemes of delegation, together with other policies and procedures and staff training arrangements, must ensure that we are told about notifiable events properly and within required timescales.

Local risk management system (LRMS) administrators have authority to submit reports to the NRLS.

We need to know the names of people who submit notifications directly to us. There is space on our forms to tell us this.

The registered person is responsible for ensuring that notifications are made; they will be committing an offence if they fail to do so. Therefore any arrangements to delegate this task must therefore be very clear.

4. Which notifications do I have to submit to CQC directly and which should I submit to the NRLS?

Notifications that must be submitted directly to CQC:

Regulation	Notification
12	Changes to the statement of purpose for an activity
15	Other changes: • plans for a new provider to carry on an activity • a new provider carries on an activity • a provider stops carrying on an activity • a provider changes their name • change of a provider's main address • change of nominated individual
17	Deaths and unauthorised absences of people detained or liable to be detained under the Mental Health Act 1983
18	Applications to deprive a person of their liberty under the Mental Capacity Act 2005, and their outcomes

Notifications that can be submitted to the NRLS:

Regulation	Notification
16	Certain deaths of people using the service
18(2)(e)	Allegations of abuse
18(2)(g)	Events that stop or may stop the service from running safely and properly
18(2)(a)&(b)	Serious injuries to people who use the activity

Making these notifications is mandatory. You will meet this requirement if you report relevant incidents to the NRLS, but you must submit them within the relevant timescale and include all the information required (see Using CQC's notification forms below).

5. **Is it mandatory for NHS providers to report all patient safety incidents to the NRLS?**	No. It is only mandatory to submit reports about the events and incidents shown in the tables above and described in detail in the Guidance about compliance: essential standards of quality and safety.
	These reports are about the most serious of the incidents previously reported under voluntary arrangements.
	Reports about other kinds of events will continue to be made under the NRLS's voluntary arrangements.

6. **Do deaths of people detained under the Mental Health Act have to be notified to both the NRLS and CQC?**	The law says that deaths of all people detained under the Mental Health Act must be notified to CQC.
	You may also need to report the death to the NRLS when a detained patient dies and there is also a relevant patient safety incident. You should use or quote the report number generated by your local risk management system (LRMS) when notifying CQC, so that duplicated notifications can be spotted if they are followed up.
	You should also use the same report number when reporting these deaths to your LRMS or the NRLS, so that duplicated notifications can be spotted when statistics are recorded and analysed.

7. **How do I submit a report to the NRLS?**	You can submit incident reports to the NRLS through your LRMS and/or relevant NRLS 'eForms'.
	These forms are still available at the NPSA website (http://www.nrls.npsa.nhs.uk). Click on links to report an incident to the National Reporting and Learning Service and then the appropriate report form.
	The eForm guides you through the reporting process and helps to ensure that you submit all the required information.

| 8. **How do I submit a notification directly to CQC?** | Appropriate staff in NHS organisations must use the Microsoft Word forms available on our website to submit notifications directly to us. We will be introducing online webforms in due course so that you can submit notifications directly from our website. |

There is more information about submitting notifications on our website.

There are separate arrangements in relation to 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 inform our Mental Health Act monitoring functions. You can download the notification forms for these and see more information about how to submit them on the mental health notifications pages on our website.

You should assign your own reference number or code to the space provided at the top of each form. We ask you to keep a record of this code so that if we ask you for more information about the incident, event or change, you can look it up more easily.

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

HSCA_notifications@cqc.org.uk

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

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

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9. 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 directly to CQC, you can send the information to the notifications email HSCA_notifications@cqc.org.uk or post it to us at:

HSCA Notifications
Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

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

If you give us more information about a notified event or contact us about it, you should always quote the reference number you assigned to the original notification (or local risk management system reference number for notifications submitted to NRLS).

If you submit additional information o the NRLS, it will be forwarded to CQC automatically.

10. Why do notifications have to be submitted using ID codes instead of people's names?	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 you 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 to 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 a code, it must not easily identify the person, such as by using their room number or date of birth.
11. 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 notifications forms using the 'equality strands' widely used across government and the economy. You should already have collected this information when accepting or admitting people under Outcomes 1 and 4 of the guidance about compliance ('respecting and involving' and 'care and welfare' of people who use services), so it should be readily available.

12. 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 the Department of Health have published *the Health Protection Legislation (England) Guidance 2010,* which explains what needs to be notified to the HPA. You should read this 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 appropriate NHS trust staff.

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

13. 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 use the search function on our website to see a continuously updated version of the regulations

Using the CQC notification forms

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

You can move from field to field when filling the CQC forms in on a computer 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. The copy and paste function works normally, but you can't use spelling and grammar checking, bullet points and numbered lists in protected forms. I 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 form.

To tick a box, use the space bar when the box is highlighted or left click on it with a mouse.

15. How do I make changes to a statement of purpose? (Regulation 12)

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, and attach them both to an email and send to us.

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

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

16. How do I tell CQC about absences of registered managers (and returns from absence) of 28 days or more? (Regulation 14)

Registered managers working for NHS bodies must use our standard form to notify us about relevant absences (and arrangements for managing the activity during the absence) and for telling us that they have returned from a notified absence.

Regulation 14 timescales:

- Notifications about planned absences of 28 days or more must be submitted **28 days before they begin**.

- You can agree shorter timescales 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 beginning of the absence.

- Where a required absence notification has not already been submitted, it must be sent to us **immediately**.

- Returns to work from an absence must be notified within **seven days**.

If the absence of a registered manager is likely to be lengthy but you are not sure how long it will last, you can propose a date by when – if the absent person has not returned to work – a new manager will be appointed and apply for registration. We will review the proposed date and agree it if it is appropriate, or discuss the matter with you if not.

| **17. How do I make changes to my registration details? (Regulation 15)** | There is a standard form, Changes to a provider's or manager's registered details, that allows you to make notifications about a 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 must fill in section 1 in all cases. The other sections of the form that NHS organisations might need to use are:

Section	Change
2	To notify a change or planned change of provider for an activity
5	To notify changes to an NHS body's: • name • business address • nominated individuals
8	To notify the details of a new Chief Executive

You can use section 11 to clarify anything, or to give us any additional relevant information.

| **18. Death of a person who uses the service (Regulation 16)** | You should notify relevant deaths to the NRLS using your LRMS or relevant eForm on the NPSA website. These reports must meet the standards for the relevant mandatory fields.

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

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

These notifications are dealt with under a separate process from that used for most notifications. This is because they inform our statutory Mental Health Act monitoring duties. You can get more information about this on our website.

If you report these deaths to your LRMS and the NPSA as well as CQC, you should use the same report number, so that we can avoid duplicating death statistics.

Unauthorised absences need only be reported by secure settings.

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

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20. How do I report 'other incidents'? (Regulation 18)

The law says that you must notify us **without delay** about a variety of 'other incidents' that take place while a regulated activity is being delivered or as a consequence of an activity being delivered.

Injuries

You should notify relevant injuries to the NRLS using your local risk management system (LRMS) or the relevant eForm on the NRLS/NPSA website. These reports must meet the standards for the relevant mandatory fields.

Deprivation of liberty applications and outcomes

There is a standard form on our website to notify us about applications to deprive a person of their liberty under the Mental Capacity Act 2005, including the outcome of the applications.

You can use this form to tell us about applications by a hospital to a 'supervisory body', or to the Court of Protection for any other setting.

Abuse and allegations of abuse

These notifications are made to the NPSA. It is important that you tell relevant local safeguarding authorities about abuse and allegations of abuse in relation to their services appropriately, as described in the *Guidance about compliance: essential standards of quality and safety*. You should include information about whether you have informed the relevant safeguarding authority about the abuse or alleged abuse in the free text 'description of what happened' field of the NPSA eForm (item IN07) or equivalent LRMS form, so that we will confirm that this has been done.

These reports must meet the NPSA's standards for the relevant mandatory fields.

Incidents reported to or investigated by the police

This notification requirement does not apply to NHS bodies.

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

You should notify relevant infrastructure problems to the NPSA using your LRMS or the relevant eForm on the NPSA website. These reports must meet the NPSA's standards for the relevant mandatory fields.

All 'other incidents' notifications must be submitted **without delay.**