

Registration under the Health and Social Care Act 2008

Notifications required by the Health and Social Care Act 2008

Guidance for English NHS providers

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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. Which notifications do NHS bodies have to submit to CQC directly and which should they submit to the NRLS?	4
3. How do NHS bodies submit notifications directly to CQC?	5
5. Who should fill in and submit notification forms?	6
6. Is it mandatory for NHS providers to report all patient safety incidents to the NRLS?	6
8. What if I need to submit more information about a notified event later on?	7
9. Why do notifications have to be submitted using ID codes instead of people's names?	7
10. Why does CQC ask about people's ethnicity, religion and so on?	7
11. Do I have to notify CQC about outbreaks of infection?	8
13. Where can I find out more about the changes, events and incidents that have to be notified to CQC?	9
Using CQC's notification forms	9
14. How are CQC's 'protected' Word document forms filled in and edited?	9
15. Changes to statement of purpose (Regulation 12)	10
16. Absences of registered managers (and returns from absence) of 28 days or more (Regulation 14)	10
17. Changes (Regulation 15)	10
18. Death of a person who uses the service (Regulation 16)	11
19. Deaths and unauthorised absences of people who are detained or liable to be detained under the Mental Health Act 1983 (Regulation 17)	11
20. 'Other incidents' (Regulation 18)	12

Summary

NHS bodies that are registered as providers and their registered managers are required to notify CQC about certain incidents, events and changes. This guidance tells you about the forms that you must use and how we process them, and how to some notifications are submitted to the National Reporting and Learning System.

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 and relevant outcomes are included in the Guidance about compliance: Essential standards of quality and safety, but 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 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.

The regulations also say that NHS bodies can submit certain notifications to the NHS Commissioning Board Authority's National Reporting and Learning System (NRLS). The NHS Commissioning Board is usually known as 'NHS England'. These notifications are then forwarded to CQC under an information sharing agreement.

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

2. Which notifications do NHS bodies have to submit to CQC directly and which should they 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: <ul style="list-style-type: none"> • 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(2)(h)	The admission of a child or young person under the age of 18 to an adult psychiatric unit or ward
18(4)(B)	Applications to deprive a person of their liberty under the Mental Capacity Act 2005, and their outcomes.

Notifications that can be submitted to NHS England's 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

Submitting these notifications is mandatory. Reporting relevant incidents to NHS England's NRLS meets this requirement. All notifications must be submitted within a required timescale and include all the information required (see 'Using CQC's notification forms' below).

3. How do NHS bodies submit notifications directly to CQC?

To submit the notifications that must be sent directly to CQC, NHS bodies must use the forms that CQC supplies. We will be introducing online forms to enable you to submit notifications in due course, and will publish guidance on how to use them.

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

When the online system is available you will be able to fill in and submit notifications by logging on to your account with a username and password, which we will give you.

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

When using Word forms, you will need to assign your own reference number or code to 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 are notifying us about, you can easily look it up.

When complete, you submit an online form by clicking on the appropriate button. To submit a Word form, you must attach it to an email and send it to:

HSCA_notifications@cqc.org.uk

The forms explain which information must be submitted. They also ask for additional information that will help us to understand what has happened and how you have responded to it.

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

4. How do NHS bodies submit a report to the NRLS?

NHS providers submit incident reports to the NRLS through their LRMS and/or relevant NRLS 'eForms'.

These forms are still available at the NPSA website (www.npsa.nhs.uk). Click on links to the National Reporting and Learning Service and then the relevant report form.

The eForm guides you through the reporting process and helps to ensure that you submit all the required information.

5. Who should fill in and submit notification forms?

The regulations say that the 'registered person' (the NHS body corporate) must submit notifications. In practice, NHS bodies will need to create delegation arrangements for this obligation to be met.

NHS providers need to ensure that their 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 CQC is told about notifiable events properly and within required timescales.

Local risk management system administrators in NHS bodies have authority to submit reports to the NPSA.

CQC needs to know the name of the person who submits notifications directly to us. There is space for them to do so on our forms.

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

6. 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 in Q2 above, and described in detail in the 'guidance about compliance'. They include the vast majority of 'never events'.

You should continue to submit reports about other kinds of events under the NRLS's voluntary arrangements.

7. 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 people detained under the Mental Health Act must be notified to CQC.

Duplicate reporting may be needed when a detained patient dies and there is a relevant patient safety incident. NHS providers should use or quote the report number generated by their local risk management system (LRMS) when notifying CQC, so that duplicated notifications can be spotted if they are followed up.

NHS providers should use the same report number when reporting these deaths to their LRMS or the NRLS, so that duplicated notifications can be spotted when statistics are recorded and analysed.

8. 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 do so to the notifications email address above.

Some notification forms are designed to enable registered persons 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.

You should always quote the reference number you assigned to the original notification (or LRMS reference number for notifications submitted to NRLS) when contacting us to discuss or give us more information about a notified event.

Additional information submitted to the NRLS will be forwarded to CQC automatically.

9. 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 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, 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 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 codes are used, they must not easily identify the person, such as by using their room number or date of birth.

10. 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. Health and social care services should collect 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.

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

No. But you must notify Public Health England (PHE - previously 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.

12. Do I have to notify CQC about medicine 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 for one of the following to be notified:

- 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.

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 read a continuously updated version of the regulations on our [website](#).

Using CQC's notification forms

14. How are CQC's 'protected' Word document forms filled in and edited?

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.

15. Changes to statement of purpose (Regulation 12)

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

You can do this by filling in or amending the relevant part(s) of our standard statement of purpose template (or amending your own alternative document), filling in the change of statement of purpose notification form, and attaching all of these to an email to send to us.

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

16. 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 to tell 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**.
- Shorter timescales can be agreed with us where appropriate – providers must contact us to discuss this when needed.
- Where an absence is caused by an emergency, the notification must be submitted 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 **forthwith**.
- Returns to work from an absence must be notified within **seven days**.

Where an absence is likely to be lengthy but the registered manager is not sure how long it will last, there is a space on the form to 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, agree it if it is appropriate, or discuss the matter with the provider if it is not.

17. Changes (Regulation 15)

The information fields and sections of the standard regulation 15 changes form allow registered persons to make notifications about the variety of changes covered by Regulation 15.

Notification of these changes must be submitted **as soon as reasonably practicable** and in advance of the change unless this is not possible.

Providers must fill in section 1 in all cases. The other sections of the form that NHS bodies 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: <ul style="list-style-type: none">• name• business address• nominated individuals
8	To notify the details of a new chief executive

Notifying the details of a new chief executive is not mandatory, but is extremely helpful, and we ask you to do this voluntarily.

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)

NHS providers notify relevant deaths to the NRLS using their LRMS or relevant eForm on the NPSA website. These reports must meet the NPSA's 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)

We use a separate process to deal with these notifications from that used for most notifications. This is 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 information about this [here](#).

NHS providers that report these deaths to their LRMS and the NPSA as well as CQC 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**.

20. '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

NHS providers notify relevant injuries to the NPSA using their local risk management system (LRMS) or the relevant eForm on the NPSA website. These reports must meet the NPSA's standards for the relevant mandatory fields.

Deprivation of liberty applications and outcomes

There is a standard CQC form for notifying applications to deprive a person of their liberty under the Mental Capacity Act 2005, including the outcome of the applications.

NHS providers 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

NHS providers make these notifications to the NPSA by. It is important that providers tell relevant local safeguarding authorities about abuse and allegations of abuse in relation to their services appropriately, as described in the guidance about compliance. 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 can 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

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

The admission of a child or young person 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 of more than 48 hours.

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