Controlled drugs

This section provides information about our role and the legal responsibilities of healthcare providers that handle controlled drugs.

What we do

We make sure that controlled drugs are managed safely. We do this by:

- checking how different regulators and agencies work together
- giving guidance and tools to healthcare providers
- leading the Controlled Drugs National Group
- reporting to the government about how partner organisations work together
- assessing and overseeing how health and social care providers manage controlled drugs
- taking part in local intelligence networks led by NHS England. These networks bring together organisations from:
    - NHS and independent health sectors
    - responsible bodies, regulators, and agencies, including the General Pharmaceutical Council, NHS Counter Fraud Authority and police services.

Our reports

View our latest report on the safer use of controlled drugs which highlights our regulatory oversight activities and assessment findings.

The law

Visit GOV.UK to view UK government legislation:

Health Act 2006: Part 3 Chapter 1

The Misuse of Drugs (Safe Custody) Regulations 1973

Misuse of Drugs Regulations 2001

Regulations Statutory Instrument 2013 No. 2013/373

Government guidance

View the Department of Health's guidance on controlled drugs regulation.

Relevant websites

Department of Health

General Pharmaceutical Council

Health Professions Council

Medicines and Healthcare products Regulatory Agency

NHSBSA Prescription Services

NHS Counter Fraud Authority

NHS England

NICE medicines and prescribing support

Nursing and Midwifery Council

Public Health England

The Home Office

See also

Cannabis-based medicinal products

Provider guidance and tools

Here we list information, guidance and tools to help you manage controlled drugs safely.

Adult social care

Care home advice

Home care advice

Primary care

GP mythbusters

Dental mythbusters

Primary care self-assessment tool

Secondary care

Secondary care self-assessment tool

Home Office controlled drugs licences

If your service handles stocks of controlled drugs, you might need to have a Home Office controlled drugs licence. The Home Office Drugs and Firearms Licensing Unit (DFLU) issue these licences.

Holding stocks of controlled drugs

'Controlled drugs stock' refers to controlled drugs that a service holds that have not already been prescribed, administered, and/or supplied to individual people. Services hold these drugs as stock for future use.

The service can use the stock for administration, such as:

- during surgical procedures
- to supply to patients, for example, when a service discharges a patient.

'Stock' can be:

- a single box of one formulation of a medicine

- multiple packets of different medicines containing controlled drugs.

If you only handle patients' own controlled drugs, you do not require a Home Office licence.

Patients' own controlled drugs are those that have been personally prescribed and supplied to them. Record-keeping, witnessed destruction and 'safe custody' may still apply to patients' own controlled drugs, depending on what schedule they fall into.

If your service needs a controlled drugs licence, you must apply for it as soon as possible. If you do not have a licence and you need one, you may not have permission to hold stock of controlled drugs or receive them from wholesalers. This could affect the provision of certain treatments or services.

Examples of services that may need Home Office controlled drugs licences include:

- NHS and private hospitals and ambulance services
- private primary care clinics
- out-of-hours doctors' services
- care homes providing nursing care.

Guidance on the application process is on the Home Office website.

Timescales for licence applications

It can take at least 6 months from the point of applying for a licence to receiving one, even if you have everything ready at the time of your application. This is because the process for obtaining one is intelligence-based and requires a physical site visit.

DFLU complete their own checks. This happens even if you have licences, registrations or authorisations with other agencies. Some services require a site visit by the DFLU as part of the application process. Once you submit an application that has been accepted as valid, DFLU will contact you within **16 weeks** to arrange the visit.

It is important to provide all information accurately and promptly to ensure your application is not delayed.

DFLU have advised:

- all first-time licensees, new sites and upgrades require a licensing visit
- renewal applications will have a visit every 1 to 5 years or more at the Home Office's discretion
- applications are only considered complete where all component parts of an application are correct and present
- if there is a delay because the Home Office has asked for more information regarding your application, it will take longer than 16 weeks to contact you to book a compliance visit.

New services

If you are a new provider and are registering with CQC and require a Home Office licence, you must apply for your licence as soon as possible.

You can apply for the licence while doing your CQC registration application. When applying for your controlled drugs licence, the DFLU will require evidence that you are in the process of obtaining your CQC registration.

You should:

- include as much information as you can on the application form

- have ready copies of correspondence with CQC, which you will need to supply on request.

Licence renewal for existing services

You must make an application for renewing a licence in good time. The covering letter issued with the controlled drugs licence indicates at the renewal stage whether a compliance visit will be necessary.

Where a visit is not required, you should submit an application at least 8-10 weeks before the expiry of your existing controlled drugs licence.

Where there is a visit required, you should submit an application at least 16 weeks before the expiry of your licence.

An automated 'reminder' email may be sent to your registered contact address up to 4 months before the expiry of your licence. If the person who is the registered contact for licences is no longer employed at your service, you may not receive a reminder email. Your service should have a process in place to identify when licences are due for renewal and to proactively update any personnel changes, obtaining new licences if needed.

If you are an existing licensee and you submit a replacement licence application before your previously issued licence expires, you can continue with your day-to-day business. You may continue operating under the conditions of your existing licence until consideration of your replacement licence application has been completed. This is on the condition that:

- your application has the same schedules and activities
- none of the details that are on your current licence have changed.

Please refer to your licence and any conditions within it for relevant details.

Changes to your licence

Changes that are a result of a sale or transfer of a service or organisation will likely invalidate your licence. You will need to apply to amend your licence. Examples of changes could include:

- a change of address
- a change of company registered address
- a change in service name or change in legal entity (where you are being given a new Companies House number).

Ensure you apply to amend your licence at the earliest opportunity. Do not wait for Companies House to complete the relevant changes. This could delay the new licence application process and your service's legal right to obtain and store controlled drugs.

If your company is a new legal entity, you will need to register for the Home Office drugs licensing system under the new legal entity company name before applying for a controlled drugs licence. If your application to register is accepted, you will be able to apply for a controlled drugs licence.

Evidence in support of your controlled drugs licence application

Provide the DFLU with evidence of your CQC registration.

If you are already registered with CQC

Upload a copy of your CQC registration certificate when applying for a controlled drugs licence.

If you are in the process of registering with CQC

Provide the DFLU with your CQC application confirmation reference and any supporting evidence relevant to the application. The CQC application confirmation reference will be a number or application validation reference. Once registration with CQC is complete, provide DFLU with your new registration certificate.

If you are making changes to your registration

When you apply for changes to your licence:

- provide the DFLU with your CQC enquiry reference
- provide the team with your new registration certificate when it arrives.

Changes include a change of name, address or the addition of another location.

Expedition of cases

Expedition of cases is reserved for only the most clinically imperative circumstances. The Home Office has provided a form you can use to request your application to be expedited.

DFLU have advised:

- Providers must not rely on this process, but instead plan ahead for any service changes.
- Provision of healthcare services is not an automatically accepted reason for expedition of an application.
- You must be able to explain:
    - which procedures are ‘clinically imperative’
    - what alternative methods or locations of service delivery are available and the reasons you consider these cannot be utilised.

Controlled drug accountable officers

Controlled drug accountable officers (CDAOs) are responsible for managing all aspects of controlled drugs in their organisation.

The roles and responsibilities of CDAOs, and the need to appoint them, are governed by the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

Organisations that must appoint a CDAO and then register their details with us:

- NHS trusts
- Independent hospitals in England
- NHS England Local Area Teams
- Headquarters in England of the regular or reserved Armed Forces

Who can be a CDAO

A CDAO must:

- be a senior manager of their organisation
- not routinely supply or handle controlled drugs themselves as part of their duties as an employee or officer.

A group of designated bodies of the same type can jointly nominate and appoint a CDAO. Each designated body within the group must notify us of the CDAO.

Social enterprise organisations (SEOs) and Community Interest Companies (CICs) must appoint a CDAO for locations that the regulations defined as a 'hospital'. In other cases they could appoint a lead to ensure controlled drug governance arrangements are in place.

CDAO notification form

When and how to tell us about changes to your controlled drugs accountable officer

How to notify us

This form is protected. Contact us at enquiries@cqc.org.uk with your name, role and organisation, and we will email the authorisation code to you.

Notify us online

After you have submitted your completed form, we will email a PDF copy of the form to you containing the information you have submitted. If you do not receive this within 48 hours of submitting your form, or you have difficulty accessing or completing the form, please email enquiries@cqc.org.uk.

When you need to inform us about changes

You must use our online form to tell us if you:

- appoint a new CDAO (whether permanent or temporary)
- re-register with us (when your organisation re-registers with us you will need to submit a new CDAO notification)
- remove a CDAO.

The CDAO position must remain filled at all times.

Changes to your CDAO's contact details

Let us know changes to your CDAO's phone number or email address by emailing us at CDAOregisterdata@cqc.org.uk.

You need to provide:

- the name of the accountable officer
- the name of the organisation
- amended details.

You must do this as soon as possible. Their new information will appear in the next update of the register.

We can only accept contact detail changes through this mailbox, if you are changing your CDAO you must submit an online notification.

CDAO exemption form

Some organisations do not need to appoint a CDAO. This section explains these exemptions and how to notify us.

How to notify us

This online form is protected. Contact us at enquiries@cqc.org.uk with your name, role, and organisation, and we will email you the authorisation code.

Notify us online

After you submit your completed form, we will email you a PDF copy with the information you provided. If you do not get this within 48 hours or have trouble with the form, email enquiries@cqc.org.uk.

When you can apply for an exemption

You can apply for an exemption from appointing a CDAO if:

- fewer than 10 people work at the hospital
- appointing a CDAO would cause more problems than benefits. This looks at the number of employees, level of activities, and difficulty finding a suitable person.

If you get an exemption because of fewer than 10 staff:

- your organisation will be removed from the CDAO register
- you do not need to submit more notifications unless the situation changes.

If we grant an exemption because appointing a CDAO would be disproportionate:

- it will last up to one year, ending on 31 December each year
- you must renew the exemption within one month of its expiry.

We can cancel the exemption at any time but will give you reasonable notice.

If we decline your application or cancel an exemption, you can appeal the decision in writing within one month of the date of our letter informing you of the decision.

Find out more about the controlled drug designated body exemption appeal process.

Self-assessment tools

These are Excel spreadsheets that contain macros. When you open them, select 'enable macros' to ensure the RAG (red, amber, green) ratings work.

Tool for primary care

Controlled drugs governance self-assessment tool for primary care organisations

Tool for secondary care

Controlled drugs governance self-assessment tool for secondary care organisations

Find out more

The safer management of controlled drugs: annual reports

Register of accountable officers in England

We record the details of healthcare organisations' CDAOs in a published register, which we update monthly.

View our current register:

Register of accountable officers (ods)

The Human Fertilisation and Embryology Authority maintains and publishes the details of Fertility centres' CDAOs

Legislation

Controlled Drugs (Supervision of Management and Use) Regulations 2013

Cannabis products for medicinal use

CQC provides guidance for providers who prescribe, or are considering proscribing, cannabis products for medicinal use.

Use the links below to find out what we expect and looks for:

What CQC expects from providers

Controlled Drugs National Group

The Controlled Drugs National Group is led by CQC. It looks at national controlled drugs governance in England.

It provides collaboration, consistency and assurance to government by:

- sharing intelligence
- highlighting good practice and areas of concern
- reporting on the impact of controlled drugs arrangements

Membership of the national group

Care Quality Commission

Department of Health

General Medical Council

General Pharmaceutical Council

Health and Social Care Information Centre

Her Majesty's Inspectorate of Prisons for England and Wales

Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence

Medicines and Healthcare products Regulatory Agency

Ministry of Defence

National Police Chiefs' Council

NHS Counter Fraud Authority

NHS England (including Health and Justice Commissioning)

The Home Office

UK Anti-doping

Veterinary Medicines Directorate

Sub-Groups

4 sub-groups provide expert advice to the national group and issue newsletters. They cover these aspects of controlled drugs:

- theft and fraud
- monitoring prescribing
- safe prescribing, dispensing and administration
- policy and operational issues

Sub-group members are from the national group as well as invited specialists.

Sub-Group newsletters

These newsletters report the group's findings. They point you to guidance and share examples of good practice and local initiatives. Providers may follow different approaches based on their local needs.

Latest newsletters

Controlled Drugs National Group newsletter: April 2021

Controlled Drugs National Group newsletter: December 2020

This gives an example of how a specific organisation responded locally to safety concerns around Alfentanil.

Controlled Drugs National Group newsletter: July 2020

Controlled Drugs National Group newsletter: April 2020

Controlled Drugs National Group newsletter: December 2019

Controlled Drugs National Group newsletter: July 2019

Controlled Drugs National Group newsletter: December 2018

Controlled Drugs National Group newsletter: August 2018

Controlled Drugs National Group newsletter: May 2018

Controlled Drugs National Group newsletter: volume 2, December 2017

Controlled Drugs National Group newsletter: volume 1, September 2017

Previous newsletters and guidance

See our earlier newsletters and guidance on safety incidents and checklists on the National Archives.

Useful links and guidance

Legislation and guidance on GOV.UK

The Misuse of Drugs Regulations 2001
The Misuse of Drugs (Safe Custody) Regulations 1973
The Controlled Drugs (Supervision of Management and Use) Regulations 2013

National Institute for Health and Care

The National Institute for Health and Care Excellence NG46 guidance

Department of Health and Social Care guidance

Controlled Drugs (Supervision of management and use) Regulations 2013