The safer management of controlled drugs
Annual report 2014

July 2015
The Care Quality Commission is the independent regulator of health care and adult social care services in England.

Our purpose
We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role
We monitor, inspect and regulate services to make sure they meet fundamental standards of quality and safety and we publish what we find, including performance ratings to help people choose care.

We also have a statutory duty to oversee the safe management arrangements for controlled drugs in England.

Our values
- Excellence – being a high performing organisation.
- Caring – treating everyone with dignity and respect.
- Integrity – doing the right thing.
- Teamwork – learning from each other to be the best we can.
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Foreword

This eighth annual report provides a national picture on the regulation of controlled drugs in England. The Care Quality Commission has a responsibility to make sure that health and social care providers, and other regulators, maintain a safe environment for the management of controlled drugs. Our priority is to protect people from unsafe care and we take this responsibility seriously. This is why our Controlled Drugs team and Medicines Management Team have worked constantly to fulfil our organisational role under the controlled drugs regulations, as well as supporting CQC’s wider inspections under the Health and Social Care Act.

It is vital that we have a governance system that can pick up concerns about the misuse of controlled drugs, but at the same time can ensure that health and care staff have proper access to them when needed for people’s clinical care.

The current regulations and governance arrangements for controlled drugs were implemented in response to the Shipman Inquiry to support professionals and encourage good practice around management and use. The regulations have created strengthened cooperation between health and social care providers and the organisations that regulate them. But in the last eight years we have seen diminishing resources, changes to the structure of the NHS, and ever-broadening complexities of the therapeutic use – and misuse – of controlled drugs. This provides continual challenges for healthcare professionals in the safe management and use of controlled drugs.

To respond to these challenges Care Quality Commission has made recommendations – both for ourselves and for other organisations – to make sure that we keep on working collaboratively and that the arrangements for controlled drugs in England continue to keep people safe.

Professor Steve Field CBE FRCP FFPHM FRCGP
Chief Inspector of General Practice responsible for Primary Medical Services and Integrated Care
Summary and recommendations

As well as regulating health and care services under the Health and Social Care Act 2008, the Care Quality Commission (CQC) is responsible for making sure that health and social care providers, and other regulators, maintain a safe environment for the management of controlled drugs in England. This was in response to the findings of the Fourth report of the Shipman Inquiry and the Government’s response to the inquiry’s recommendations.

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force on 1 April 2013. This report looks at the work of CQC and other responsible organisations during 2014 under these regulations to ensure safe arrangements for controlled drugs. It also reports on prescribing data for 2014 on controlled drugs across England and identifies any trends in prescribing.

One of CQC’s responsibilities around controlled drugs is to maintain and update the register of controlled drug accountable officers (CDAOs), who are responsible for all controlled drug handling and governance issues in their organisation. Some small organisations are exempt from the need to have a CDAO, but uptake of this exemption during 2014 was low. Another responsibility for CQC is the need to work with local controlled drug intelligence networks (CD LINs) across England, and to work with lead CDAOs to identify organisations that do not engage with their CD LIN and do not provide occurrence reports. We continued to identify and follow up where a CDAO had left an organisation but where we had not received a new notification for the replacement CDAO.

CQC coordinates the National Group on Controlled Drugs, which met four times during 2014. The Clinical Sub Group met twice and the methadone newsletter was published on CQC’s website. We also met twice with our cross border colleagues in Wales, Scotland, Northern Ireland, Republic of Ireland, the Channel Islands and the Isle of Man, to share good practice and discuss controlled drugs-related issues.

CQC has created self-assessment tools to enable primary and secondary care organisations to establish areas of strength or weakness in their controlled drug governance arrangements. We updated these in 2014, to use a more user-friendly red, amber, green (RAG) rating.

This was the first full year under the 2013 Regulations and the new arrangements as set out in the NHS England Single Operating Model (SOM), which provides a framework, guidance and templates for lead CDAOs on their roles and responsibilities. There were 27 NHS England area teams in 2014, but after an organisational capacity review of NHS England in the latter part of the year, some areas amalgamated to form 13 new regions from April 2015.
Although this has caused some concern in terms of the size of the regions that each NHS England lead CDAO is required to cover, it also provides an opportunity for better collaboration between lead CDAOs and a more joined up approach to sharing good practice. Despite some variation during 2014 in how the area teams fulfilled their functions, CD LIN meetings and learning events were held across all area teams and concerns were shared and followed up. However, in general, there continued to be only minimal engagement with social care organisations and a lack of capacity to monitor controlled drug prescribing.

Discussions continued during 2014 on the feasibility of a national roll-out of the Greater Manchester Area Team (GMAT) reporting tool across England. Consequently, the joint work between CQC and NHS England to collect national occurrence reporting data has been suspended until those discussions are concluded. We will then review how best to gather the national picture.

**National trends in the use and management of controlled drugs**

In 2014, the total number of controlled drugs items prescribed in NHS primary care was 60,871,306, which is an increase of 0.67% compared with 2013. The cost of this was £548,634,970, representing a decrease of 0.37% compared with £550,684,964 in 2013. Prescribing of all Schedules (2, 3, 4 and 5) of controlled drugs in 2014 stayed broadly similar to that in 2013.

There were a number of legislation changes in June 2014, which included the scheduling of tramadol from a prescription only medicine (PoM) to a Schedule 3 controlled drug; zopiclone and zaleplon were also scheduled under Part 1 of Schedule 4 alongside zolpidem following control; and lisdexamfetamine was scheduled as a Schedule 2 controlled drug alongside dexamfetamine. In addition, the N-benzylated phenethylamines (NBOMe) and benzofuran compounds (advertised for sale as ‘legal highs’) were listed in Schedule 1 to the 2001 Regulations and designated as drugs to which section 7(4) of the 1971 Act applies as they have no known legitimate uses outside of research. This means they can only be possessed or supplied under a Home Office licence for research of other special purpose.

Prescribing by nurses increased by 12% and prescribing by pharmacists increased by 56% in 2014 compared with 2013. However, this still represents only a small proportion of total controlled drug prescribing. Nurses and pharmacists are principally involved in prescribing methadone and buprenorphine for the treatment of addiction, which accounts for the majority of prescriptions for controlled drugs from these two groups.

Private prescribing accounts for a small proportion of overall controlled drug prescribing (about 0.06%). The total number of Schedule 2 and 3 controlled drug items prescribed privately in 2014 was 38,913, which is an increase of about 5% compared with 2013. The overall pattern of private prescribing was similar to that reported in 2013.
Practitioners working in healthcare settings in the community who wish to obtain a stock of a Schedule 2 or 3 controlled drug from a community pharmacy should use a standard Controlled Drug Requisition Form (FP10 CDF). However, use of these forms will not be mandatory until 30 November 2015 and pharmacies can supply controlled drugs requisitioned on non-standard forms. This makes the capturing and analysis of the data more difficult. However, the requisition data that we do have shows that 19,323 controlled drug items were requisitioned in 2014, which is only a small increase of 1% compared with 2013.

2014 was a settling down period in which NHS England lead CDAOs worked hard to ensure that the arrangements for the safe management of controlled drugs were maintained following the restructure of the NHS and changes in regulations during 2013.

Going forward, the further restructure of NHS England must be seen as an opportunity for greater collaboration and consistency across England.

We therefore make the following recommendations.
Recommendations

Recommendation for CQC

- CQC should make information available to small organisations to advise them of the exemption provision in the regulations for the need to appoint a controlled drug accountable officer.

Recommendations for NHS England lead controlled drug accountable officers

- NHS England lead controlled drug accountable officers should use the changes to the regional structure from April 2015 as an opportunity to work more collaboratively so that there is greater national consistency of approach to delivering their controlled drug responsibilities.
- NHS England lead controlled drug accountable officers should engage with and formalise the support of clinical commissioning groups (CCGs) so that monitoring controlled drug prescription activity is a higher priority.
- NHS England lead controlled drug accountable officers should determine how best to engage with social care organisations in their area and should encourage local authorities to be engaged in controlled drug local intelligence networks (CD LINs).

Recommendations for NHS England

- NHS England should provide guidance for occurrence reporting so that organisations understand what they need to report to the CD LIN.

Recommendation for all controlled drug accountable officers

- Controlled drug accountable officers should share organisational learning from controlled drug-related incidents with their CD LINs and, where possible, develop links with their Medication Safety Officers (MSOs) to maximise these opportunities for learning.
Progress on recommendations made in the 2013 report

In the report for 2013, CQC made seven recommendations to improve the management of controlled drugs. In this section, we report on the progress made against these.

**Recommendation 1**

*NHS England controlled drug accountable officers must be adequately resourced to carry out their roles and responsibilities with regard to controlled drugs.*

**Progress:**

During 2014, NHS England controlled drug accountable officers (CDAOs) found a number of ways to carry out their responsibilities. These included secondments, informal arrangements with clinical commissioning groups (CCGs) and commissioning support units (CSUs) and other goodwill gestures. The changes to NHS England in 2015 provide a new opportunity for more collaborative working, which will help achieve greater national consistency as long as capacity is used effectively.

**Recommendation 2**

*NHS England controlled drug accountable officers must be clear about their responsibilities for controlled drug governance arrangements and strengthen their relationships with CCGs and CSUs so that these organisations are clear as to how they can support them.*

**Progress:**

Although CCGs and CSUs provided some support, there was a mixed picture. The arrangements for how CCGs should support NHS England CDAOs are now clearly set out in the delegation agreement for co-commissioning.

**Recommendation 3**

*NHS England controlled drug accountable officers should consider organising learning events for controlled drug accountable officer colleagues and controlled drug leads, to enable them to share learning and best practice.*

**Progress:**

Most area teams organised learning events in 2014, which CDAO colleagues and support staff found beneficial. For example, a number of area teams joined together to provide full-day events with external speakers, enabling networking, discussions and sharing good practice.
Recommendation 4

NHS England controlled drug accountable officers should consider extending membership of the controlled drug local intelligence network to other relevant local organisations (such as social enterprise organisations or community interest companies) either on a permanent or ‘as required’ basis.

Progress:
Most controlled drug local intelligence networks (CD LINs) have broadened the membership of the open part of their meetings to include all relevant organisations across their patch, leading to a greater awareness of the issues faced by different services and a richer discussion of controlled drug-related issues.

Recommendation 5

A formal process should be put in place by NHS England controlled drug accountable officers to ensure controlled drug concerns and good practice are shared nationally where appropriate.

Progress:
Although information was shared well across the boundaries of CD LINs during 2014, there was no formal process in place to share concerns and good practice nationally. From 1 April 2015, this will be more easily achieved as all NHS England lead CDAOs will be members of the NHS England National Controlled Drugs Forum.

Recommendation 6

Healthcare providers must determine whether they are required to appoint a controlled drug accountable officer or whether they meet the criteria for an exemption.

Progress:
The uptake of the exemption facility remains minimal and CQC will review how best to inform and advise small providers about this.

Recommendation 7

The Care Quality Commission should summarise the key messages from the Controlled Drugs National Group meetings and circulate them to NHS England controlled drug accountable officers to pass on to members of their controlled drug local intelligence networks.

Progress:
CQC has circulated a summary of the minutes after each meeting, which have been well-received by CD LIN members. However, we are aware that the minutes are not always shared further across organisations and we encourage each CD LIN member to share the minutes with other relevant staff in their organisation as necessary.
Activity from the Care Quality Commission

CQC’s website

There is a dedicated section on CQC’s website about controlled drugs, which includes:

- Guidance for accountable officers – who should be a CDAO, which organisations need a CDAO and which are exempt.
- Guidance on making notifications and the associated web-based forms.
- The register of CDAOs.
- Self-assessment tools.
- Links to the legislation and supporting information.
- Previous annual reports.
- Clinical sub-group newsletters.
- Primary medical services ‘Controlled drugs myth-buster’.

We have been monitoring the number of visits to this section on the website since May 2014, which receives an average of about 2,000 views each month.

Figure 1: Number of visits to CQC’s controlled drugs web pages from May 2014
Primary and secondary care self-assessment tools

Both the primary care self-assessment tool and the secondary care self-assessment tool were updated in 2014 to reflect changes to the NHS structure and to make them easier to use by replacing the numerical scoring system with a red, amber, green (‘RAG’) rating. We launched the new tools on 1 August 2014 – initially as a pilot for six months while we gathered feedback from users. The number of downloads averaged at 200 a month.

Register of controlled drug accountable officers (CDAOs)

As required under the 2013 Regulations, CQC continues to maintain and publish a list of CDAOs across England. Organisations that are required to have a CDAO (called controlled drug designated bodies) must notify CQC of their appointment and any ongoing changes to their CDAO to enable us to keep the register up to date. The CDAO register, the notification webform and associated guidance are all available on our website and further help and clarification is also available by emailing CQC’s Controlled Drugs team at CDAORegisterData@cqc.org.uk. Changes of contact details can also be emailed to this address.

During 2014, we updated the register every month and received 261 notifications about CDAOs, of which 192 were from independent healthcare organisations.

The 2013 Regulations also made a new provision for exemptions to the requirement to appoint a CDAO for small businesses (those with fewer than 10 staff) and for businesses with more than 10 staff, but where it would be disproportionate to appoint someone as the controlled drug usage is low. Where the exemption is based on size, we ask organisations to notify us so that we can remove them from the register. In some cases – even though an organisation may have more than 10 staff – it would be disproportionate to appoint a CDAO. In these cases, we ask them to notify us so that we can consider granting a time-limited exemption, during which we remove the organisation from the register. Exemptions are granted on a case-by-case basis and are for a period of up to one year (ending 31 December each year), after which time we ask the organisation to re-apply. Uptake of this provision has and continues to be low and we believe this is because smaller organisations are less aware of the exemption provision.

We received 14 exemption requests in 2014. To date, all exemptions applied for have been granted.

Recommendation for CQC

- CQC should make information available to small organisations to advise them of the exemption provision in the regulations for the need to appoint a controlled drug accountable officer.
Arrangements with NHS England and controlled drug local intelligence networks

All NHS England lead CDAOs carried out their role during 2014, but there was considerable variation across the area teams despite implementation of the Single Operating Model (SOM). Although resources remained limited, most lead CDAOs managed to secure some form of dedicated support resource. Clinical commissioning groups (CCGs) and commissioning support units (CSUs) also carried out controlled drug-related duties on behalf of the area teams, although these arrangements were generally based on goodwill rather than anything more formal. The majority of lead CDAOs reported a lack of capacity to undertake prescription-monitoring activity in any detail and although the NHS Business Services Authority has provided prescribing reports since August 2014, capacity to monitor and follow-up prescribing concerns remains an issue.

CQC attended 96 controlled drug local intelligence network (CD LIN) meetings across all area teams during 2014. We saw that meetings were being held regularly, with most held between two and four times during the year with associated learning events. There was generally good engagement between organisations and regulators and many CD LINs had noticeably wider memberships (although some smaller organisations have poor attendance at meetings). However, some lead CDAOs reported that they found it difficult to engage with their local authorities – this is particularly important for gaining intelligence regarding social care organisations across the area. In some areas, lead CDAOs are linking with local Drug Related Death Groups and are sharing the learning from these groups with CD LIN members.

Recommendations for NHS England lead controlled drug accountable officers

- **NHS England lead CDAOs should use the changes to the regional structure from April 2015 as an opportunity to work more collaboratively so that there is greater national consistency of approach to delivering their controlled drug responsibilities.**

- **NHS England lead CDAOs should engage with and formalise the support of clinical commissioning groups (CCGs) so that monitoring controlled drug prescription activity is a higher priority.**

- **NHS England lead CDAOs should determine how best to engage with social care organisations in their area and should encourage local authorities to be engaged in controlled drug local intelligence networks (CD LINs).**
Examples of good practice from CD LINs

When we attend CD LIN meetings, we ask members to share good practice initiatives with us so that we can include them in our report and share the learning with other organisations. The following are some examples we saw in 2014.

Good practice initiative 1: East of England Area Team

The Controlled Drug Liaison Officer (CDLO) covering the geography of the East of England Area Team challenged Basildon & Thurrock University Hospitals NHS Foundation Trust about the frequency of ward controlled drugs checks and whether they should be increased from daily to every shift change. The Chief Pharmacist found that the trust was in line with the majority of other trusts in making a daily check, but this led to her develop a questionnaire, which is now in use across the whole of East of England, and which has enabled 15 NHS trusts to share aspects of their controlled drugs policies relating to:

- Ward checks.
- Handling of patients own controlled drugs.
- Training for nurses about controlled drugs.
- Anticipatory medicines.
- Handling of non-Schedule 2 controlled drugs.

The questionnaire is going to be further developed to include other areas such as destruction and security of controlled drugs in departments that are not manned 24 hours a day, seven days a week.

Good practice initiative 2: Cumbria, Northumberland, Tyne and Wear Area Team and CSU

The North of England Commissioning Support Unit, supported by the lead CDAO within Cumbria, Northumberland, Tyne and Wear Area Team, developed a system for categorising incidents relating to controlled drugs that were reported to them and produced a report of their findings. They categorised the incidents into the following groups: suspected fraudulent activity; balance discrepancies; dispensing, administration or prescribing errors; substance misuse errors and governance concerns. They then looked at the controlled drugs involved in each category and the types of incidents in more detail to gain a better oversight of occurrence reporting across their area. This work was presented at their learning event and the NHS England learning event in December 2014.
Good practice initiative 3: NHS Cambridgeshire and Peterborough Clinical Commissioning Group

This CCG has produced 10 ‘Controlled Drug Factsheets’ for GP practices. They cover different aspects that are important for GPs such as storage, record-keeping, and doctors’ bags. This example shows information about destruction of controlled drugs.

### Controlled Drug Factsheet

**Destruction**

Before disposing of Schedule 2, 3 and 4 (part 1) CDs they must be denatured so as to make them unrecoverable.

Stock Schedule 2 CDs must be denatured in the presence of an **Authorised Witness**.

Stock Schedule 3 and 4 (part 1) CDs and CDs returned by patients can be denatured in the presence of a witness from the practice.

The destruction and disposal of CDs are subject to the Waste Management Licensing Regulations 1994 and the Hazardous Waste (England and Wales) Regulations 2005. Destruction of CDs requires an exemption to the licence, a T2B exemption. The exemption needs to be registered with the Environment Agency [https://www.gov.uk/environmental-permit-how-to-apply](https://www.gov.uk/environmental-permit-how-to-apply)

To request a visit from an authorised witness, please contact the Medicines Management Team and ask for Clare Moody:

01480 387 114

Ensure you have allocated sufficient time to complete the task **uninterrupted**. Prepare a clean and clear work space, and work in an orderly fashion. Always read instructions on DOOP® container before you start.

For Schedule 2 CDs, count and record quantity of items being destroyed in the controlled drug register or patient returns register. No records are required for 53 or 54 p1 CDs.

Ensure each drug is destroyed separately and each task is completed (including register entries) before moving on to the next.

When all items have been added to the DOOP® container, add water to the level indicated on the container, seal and shake until the mixture has become solid. Where instructions indicate to fill container to capacity with water, fill to the brim – the gel shrinks when in solidifies. Alternatively, where instructions indicate, do not fill above the maximum fill line.

Following Instructions on the container either place DOOP® container in the yellow pharmaceutical waste bin or return to the CD cupboard for stated length of time.

For larger volumes of liquid, denaturing kits are available up to 2L capacity.

Contact the Medicines Management Team for advice: Clare Moody, care.mood@nhs.net, 01480 387 114

Controlled Drug Accountable Officer: Dr Melanie Clements-England, care.cda@nhs.net
Good practice initiative 4: Bristol, North Somerset and South Gloucestershire Area Team

The lead CDAO for this area team looked at the use of controlled drugs in social care organisations across her area. She looked at:

- How problems were exacerbated by the frailty and vulnerability of the patient group.
- High staff turnover and use of agency staff.
- A general lack of training for staff in medicines administration.
- The effect of minimal support from pharmacists.

The CDAO wrote to care homes in the area to engage with them and to encourage better reporting of controlled drug incidents. She identified the need to raise the profile of controlled drugs issues in social care with NHS England, so that this work can be taken further at a national level. Her work was presented at the NHS England learning event in December 2014.

Part of the Care Quality Commission’s oversight role, as well as contributing to the work of CD LINs, is to review how effectively they are working. We compiled an overview report for NHS England on what we found, which echoes our recommendations in the 2013 annual report around the need for appropriate resources to enable CDAOs to perform their responsibilities effectively and for clear arrangements with other supporting organisations such as CCGs. We also gave NHS England more detailed suggestions for further development, some of which we have highlighted:

- To improve the effectiveness of CD LIN meetings, continuity of membership is essential, and organisations should, as far as possible, limit attendance to an agreed member and named deputy.
- NHS England lead CDAOs need to consider ways to engage with CD LIN members between meetings, to keep them updated on controlled drug-related issues.
- Further discussion is required at a national level to address the concerns raised by the majority of lead CDAOs who reported a lack of capacity to undertake prescription-monitoring activity and follow up on prescribing concerns.

NHS England learning events

NHS England held two learning events in June and December 2014, which were informative and well-attended, and provided a good opportunity for networking. Many lead CDAOs used the presentations for their own area team learning events.
Occurrence reporting

In 2013, CQC set out to collect high-level data on the number of controlled drug occurrences reported to each NHS England area team to enable us to see the national picture. This work has been put on hold while NHS England discusses the Greater Manchester Area Team (GMAT) reporting tool. However, in order for any data to be meaningful, national agreement is needed as to what ‘incidents’ should be reported to the CD LINs, as there is currently variation across England. Moreover, learning opportunities following the investigation of clinical incidents are often lost because many such incidents are resolved internally and not reported to the CD LINs. There would be greater learning if the incidents were discussed at CD LIN meetings and, where possible, discussed with the organisation’s Medication Safety Officer.

Recommendations for NHS England

- NHS England should provide guidance for occurrence reporting so that organisations understand what they need to report to the CD LIN.

Recommendation for all controlled drug accountable officers

- Controlled drug accountable officers should share organisational learning from controlled drug-related incidents with their CD LINs and, where possible, develop links with their Medication Safety Officers (MSOs) to maximise these opportunities for learning.

National Group on Controlled Drugs

CQC’s work involves leading a national strategic group of regulators and agencies with areas of responsibility for controlled drugs within their remit. The General Medical Council, the Health and Care Professions Council and the NHS England Pharmaceutical Adviser for Health and Justice Commissioning joined the group in 2014.

The group met four times in 2014 (March, June, September and December) to share and discuss emerging issues and to identify ways of working together to reach solutions. After each meeting, a condensed version of the meeting minutes was shared with NHS England lead CDAOs for onward cascade to CD LIN members to keep them informed of controlled drug-related developments and policy initiatives.
Membership of the Group in 2014 included:

- Association of Chief Police Officers
- Care Quality Commission
- Department of Health
- General Medical Council
- General Pharmaceutical Council
- Health and Social Care Information Centre
- Health and Care Professions Council
- Her Majesty’s Inspectorate of Prisons
- Home Office
- Medicines Advice (Medicines and Prescribing Centre) National Institute for Health and Care Excellence
- Medicines and Healthcare products Regulatory Agency
- Ministry of Defence
- NHS England (including the Patient Safety team and Pharmaceutical Adviser for Health and Justice Commissioning)
- NHS Protect
- Ofsted
- Public Health England
- UK Anti-doping
- Veterinary Medicines Directorate.

Alongside this main report, we have published a report of the activity from the group’s main partners, which shows the many ways in which these agencies contribute to the overall safer management of controlled drugs. The following are some key highlights from members of the National Group:
Home Office

The Home Office has responsibility for the Misuse of Drugs Act 1971 and its associated Misuse of Drugs Regulations 2001, which provide the framework for lawful activity with controlled drugs and drug precursor chemicals by the pharmaceutical industry and healthcare professionals. There were a number of legislation changes in June 2014,

- Tramadol was scheduled from a prescription only medicine (PoM) to a Schedule 3 controlled drug, but exempted from the safe custody requirements.
- Zopiclone and zaleplon were listed in Part 1 of Schedule 4 to the 2001 Regulations alongside zolpidem.
- Lisdexamfetamine (a drug that converts to dexamfetamine when administered orally and used as second line treatment for attention deficit hyperactivity disorder (ADHD)) was listed in Schedule 2 to the 2001 Regulations alongside dexamfetamine.
- The N-benzylated phenethylamines (NBOMe) and benzofuran compounds (advertised for sale as ‘legal highs’) were listed in Schedule 1 to the 2001 Regulations and designated as drugs to which section 7(4) of the 1971 Act applies as they have no known legitimate uses outside of research. This means they can only be possessed or supplied under a Home Office licence for research of other special purpose.

The Home Office also carried out a consultation during 2014 on ketamine, which will be rescheduled to a Schedule 2 controlled drug in 2015.

National Institute for Health and Care Excellence (NICE)

NICE published a medicines evidence commentary (MEC) in June 2014, on Amendments to The Misuse of Drugs Act 1971 affecting tramadol, zaleplon, zopiclone and lisdexamfetamine, which alerted health professionals to changing legislation on controlled drugs.

In October 2014, NICE started to develop a guideline on the safe use and management of controlled drugs. You can see information about the guideline development on the NICE website here. The guideline is scheduled for publication in March 2016.
Medicines and Healthcare products Regulatory Agency (MHRA)

Operation Pangea is an international week of action tackling the online sale of counterfeit and unlicensed medicines. Coordinated by INTERPOL, the annual operation brings together customs, health regulators, national police and the private sector from countries around the world. The UK results for 2014 included:

- UK seizures of counterfeit and unlicensed medicines totalling £9.5 million, which included 3.6 million doses of counterfeit and unlicensed medicines, including huge hauls of potentially harmful slimming pills and controlled drugs such as diazepam and anabolic steroids.
- 5 arrests.
- 1,862 websites closed down.
- Targeting, for the first time, illegal adverts on Social Media Websites.
- 18,671 YouTube videos removed and 356 YouTube accounts terminated.
- Press coverage from BBC Fake Britain, the Daily Telegraph, Reuters, Herald Scotland, the Manchester Evening News, and the Yorkshire Post.

NHS Protect

To improve its presence and engagement activity at CD LIN meetings, NHS Protect made efforts to ensure that operational staff attended each area team CD LIN meeting. A key role for NHS Protect is to engage with and provide support to CDAOs. NHS Protect staff have been able to provide support and advice to CDAOs on a number of issues including alerts, investigations, liaising with the Police, and implementing security measures.

Some incidents are reported to the Local Security Management Specialist (LSMS) and/or the Police for investigation and sanctions are applied, such as prosecution and/or disciplinary action. However, some NHS trusts do not always make use of the LSMS and other staff (clinical, administrative or managerial) carry out investigations without involving the LSMS. As a result, sanctions are not always applied, particularly where a member of staff or contractor is involved.
Clinical sub-group

The clinical sub-group to the National Group on Controlled Drugs was formed in the second half of 2012 to provide expert clinical advice for CDAOs on the safe use of controlled drugs in practice and minimising their risks and harms. It is co-chaired by CQC and the Patient Safety Team at NHS England. The sub-group comprises medical and pharmacy specialists, CDAOs and regulatory bodies.

The group met twice in 2014, and its key output in the year was the production and circulation of a newsletter and supporting information in November on preventing harm from the use of methadone. The newsletter is one of a series that builds on the work of the National Reporting and Learning System (NRLS) and provides a valuable resource, especially for preventing accidental harm to patients.

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2014. It provides a forum to discuss matters of mutual interest at a strategic level among those charged with management, monitoring or inspection of the governance arrangements for controlled drugs, and to share information such as:

- Intelligence of general concerns across national borders.
- Intelligence about emerging specific concerns that could impact on neighbouring nations.
- Learning and best practice methods that support the safer management of controlled drugs in each nation.
- Analysis of trends and associated risks pertinent to safer management and use of controlled drugs.

The following are summaries of some good practice initiatives from our cross-border colleagues.

Scotland

The Controlled Drugs Accountable Officers’ Network Scotland (CDAON) published the second edition of A Guide to Good Practice in the Management of Controlled Drugs in Primary Care – Scotland, September 2014. CDAON has linked with the Therapeutics Branch of the Scottish Government Pharmacy and Medicines department and the Scottish Prescribing Advisors Association to adapt and develop National Therapeutic Indicators (NTIs) specifically for controlled drugs. NTIs can be utilised to identify variance in prescribing and are designed to improve the quality, safety and efficiency of primary care prescribing. These controlled drug NTIs are expected to be launched in 2015/16.
CDAON (Scotland) produces ‘flash reports’ to highlight issues identified from collecting data on adverse events involving controlled drugs and areas of clinical concern. Preventing Harm from Oral Oxycodone Medicines was published in September 2014, with future publications to include methadone and fentanyl patches. These flash reports aim to minimise risks and promote patient safety and learning and can be found here.

Webpages for the Controlled Drugs Accountable Officers’ (CDAO) Network are hosted on NHS Education for Scotland (NES) Knowledge Network. These contain a wide range of documents, guidance and information relating to the safe and secure management of controlled drugs, which can be found here.

**Northern Ireland**

The Health and Social Care Board began a regional project in 2013 to develop a controlled drug record card (CDRC) with supporting guidance and patient information. The CDRC is intended to be used by nursing staff from all organisations and GPs to record stock of parenteral and transdermal Schedule 2 and 3 controlled drugs received by, and administered to, patients in the community. The final version is nearing completion, at which stage it will be shared with trusts and GPs for any additional comments and sign off. We anticipate that the CDRC will become operational towards the summer of 2015.

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 came into operation on 1 October 2009, a time of significant structural change for the Health and Social Care Board (HSCB). As a result, the Department of Health, Social Services and Public Safety (DHSSPS) undertook responsibility for the operation of Northern Ireland’s single Local Intelligence Network (LIN). In December 2014, the responsibility for the LIN was transferred to HSCB, mirroring arrangements in Great Britain. It is proposed that the HSCB’s responsibility for the LIN will be enshrined in legislation.

**Wales**

NHS Wales continued to have a focus on tramadol and opioid prescribing, with resource materials for primary and secondary care produced by the All Wales Therapeutics and Toxicology Centre. The resource materials are available on the All Wales Medicines Strategy Group web site here.

A pioneering project providing accurate information and pragmatic harm reduction advice on unknown or unidentified drugs in Wales has analysed almost 2,000 samples during its first year. The Welsh Emerging Drugs and Identification of Novel Substances (WEDINOS) project, run by Public Health Wales, has been designed specifically to collect and test new psychoactive substances (NPS) and to provide users with advice on harm reduction. Information can be found on the WEDINOS website. There is also a first annual report for 2013/14.
Ireland

The Health Products Regulatory Authority (HPRA), formerly known as the Irish Medicines Board, manages the application and issue process for controlled drug licences and registrations on behalf of the Department of Health in Ireland. The HPRA also participates in European stakeholder meetings, including representation at the Cross-Border Group. Guidance documents for stakeholders are available on the HPRA website (www.HPRA.ie).

The Pharmaceutical Society of Ireland (PSI) regulates and provides legislative and practice guidance regarding the management of controlled drugs within pharmacy services in Ireland. Annual reports, a list of Authorised Officers and guidance can be accessed on the website.

The National Advisory Committee on Drugs and Alcohol (NACDA) has an Early Warning Emerging Trends subcommittee, which advises the Irish Government on the prevalence, consequences, prevention and treatment of substance use and misuse based on analysis and interpretation of research findings. The subcommittee comprises representatives of relevant national and forensic laboratories, law enforcement agencies, relevant government departments, health services and the voluntary and community sectors. It shares information on emerging trends and patterns in drug use, particularly poly drug use and associated risks.
National trends in the use and management of controlled drugs

During 2014, CQC continued to monitor and analyse ePACT prescribing data on controlled drugs to gain an overview of the national picture across England and to identify trends in prescribing. NHS Prescription Services collects all data on prescribing in both NHS primary care and for private prescriptions for Schedule 2 and 3 controlled drugs, which are dispensed in community pharmacies.

Prescribing of controlled drugs in primary care

In 2014, the total number of controlled drugs items prescribed in NHS primary care was 60,871,306, which is an increase of 0.67% compared with 2013. The cost of this was £548,634,970, representing a decrease of 0.37% compared with £550,684,964 in 2013.

Schedule 1 controlled drugs

There are currently no controlled drugs in Schedule 1 used for medicinal purposes.

Schedule 2 and 3 controlled drugs

Prescribing of Schedule 2 and 3 controlled drugs in 2014 stayed broadly similar to that in 2013 (table 1 and figure 1). We saw increases in volume for midazolam, morphine and methylphenidate of 11%, 10% and 9% respectively and decreases of 16% and 4% for temazepam and methadone. We also saw a slight but negligible decrease in tramadol prescribing.

Methylphenidate prescribing continued to increase steadily during 2014, as in previous years. This is likely to be attributable to continuing increases in the diagnosis of, and prescribing for the treatment of attention deficit hyperactivity disorder (ADHD), although we are aware that it is also subject to misuse.

Prescribing of temazepam has continued to decline since 2007. It is likely that the non-benzodiazepine hypnotics, zolpidem, zopiclone and zaleplon, are being prescribed instead. In June 2014, zopiclone and zaleplon were re-scheduled under Part 1 of Schedule 4 alongside zolpidem but to date this has not affected prescribing.

In June 2014, tramadol was rescheduled as a schedule 3 controlled drug (with safe custody exemption) but this did not appear to affect its use.
Table 1: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by number of items)

<table>
<thead>
<tr>
<th>Top 10 Schedule 2 &amp; 3 controlled drugs</th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tramadol Hydrochloride</td>
<td>7,888,792</td>
<td>7,888,685</td>
<td>↓</td>
</tr>
<tr>
<td>Buprenorphine*</td>
<td>2,428,389</td>
<td>2,644,760</td>
<td>↑</td>
</tr>
<tr>
<td>Morphine Sulfate</td>
<td>2,188,584</td>
<td>2,406,166</td>
<td>↑</td>
</tr>
<tr>
<td>Methadone</td>
<td>2,101,722</td>
<td>2,009,688</td>
<td>↓</td>
</tr>
<tr>
<td>Temazepam</td>
<td>1,993,927</td>
<td>1,666,775</td>
<td>↓</td>
</tr>
<tr>
<td>Oxycodone**</td>
<td>1,246,400</td>
<td>1,353,362</td>
<td>↑</td>
</tr>
<tr>
<td>Fentanyl†</td>
<td>1,158,078</td>
<td>1,203,660</td>
<td>↑</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>725,816</td>
<td>793,749</td>
<td>↑</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>246,280</td>
<td>236,850</td>
<td>↓</td>
</tr>
<tr>
<td>Midazolam*</td>
<td>192,175</td>
<td>213,125</td>
<td>↑</td>
</tr>
<tr>
<td>All other Schedule 2 &amp; 3 controlled drugs</td>
<td>289,932</td>
<td>314,309</td>
<td>↑</td>
</tr>
<tr>
<td>Total</td>
<td>20,460,095</td>
<td>20,731,129</td>
<td>↑</td>
</tr>
</tbody>
</table>

* Buprenorphine figures include the combination product Suboxone (buprenorphine + naloxone), Buprenorph HCl, Buprenorphine, Buprenorphine Hydrochloride.
** Oxycodone figures include the combination product Targinact (oxycodone and naloxone).
† Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.
* Midazolam figures include oral and injectable midazolam, Midazolam Hydrochloride, Midazolam Maleate.

Figure 1: Top 10 Schedule 2 and 3 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by millions of items) (caveats as in table 1)
Schedule 4 controlled drugs

The pattern of prescribing for Schedule 4 controlled drugs during 2014 remains broadly similar to that seen in 2013. Figure 2 shows the profile of prescribing for Schedule 4 controlled drugs during 2014. Of this, 97% is accounted for by benzodiazepines and the non-benzodiazepine hypnotics (often referred to as z drugs).

Table 2: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by number of items)

<table>
<thead>
<tr>
<th>Top 10 Schedule 4 controlled drugs</th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zopiclone</td>
<td>5,529,268</td>
<td>5,657,585</td>
<td>↑</td>
</tr>
<tr>
<td>Diazepam</td>
<td>5,160,407</td>
<td>5,239,813</td>
<td>↑</td>
</tr>
<tr>
<td>Lorazepam</td>
<td>1,007,828</td>
<td>1,046,808</td>
<td>↑</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>786,032</td>
<td>835,655</td>
<td>↑</td>
</tr>
<tr>
<td>Zolpidem</td>
<td>730,752</td>
<td>734,934</td>
<td>↑</td>
</tr>
<tr>
<td>Nitrazepam</td>
<td>793,164</td>
<td>734,578</td>
<td>↓</td>
</tr>
<tr>
<td>Clobazam</td>
<td>232,952</td>
<td>248,602</td>
<td>↑</td>
</tr>
<tr>
<td>Testosterone</td>
<td>177,742</td>
<td>187,503</td>
<td>↑</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>139,101</td>
<td>121,957</td>
<td>↓</td>
</tr>
<tr>
<td>Chlordiazepoxide</td>
<td>146,143</td>
<td>117,656</td>
<td>↓</td>
</tr>
<tr>
<td>All other Schedule 4 controlled drugs</td>
<td>314,750</td>
<td>312,279</td>
<td>↓</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>15,018,139</td>
<td>15,237,370</td>
<td>↑</td>
</tr>
</tbody>
</table>

Figure 2: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by millions of items).
Schedule 5 controlled drugs

The pattern of prescribing for Schedule 5 controlled drugs during 2014 remains broadly similar to that seen in 2013.

Figure 3 shows the profile of prescribing for Schedule 5 controlled drugs during 2014. Although many of the drug substances are the same as those in Schedule 2, they are present only in small amounts and are therefore subject to a lower level of control. The most commonly prescribed Schedule 5 item continues to be co-codamol (a combination of paracetamol and a low dose of the weak opioid, codeine), which accounts for 55% of prescribing in this group.

Table 3: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by number of items)

<table>
<thead>
<tr>
<th>Top 10 schedule 5 controlled drugs</th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-codamol</td>
<td>14,024,072</td>
<td>13,744,546</td>
<td>↓</td>
</tr>
<tr>
<td>Codeine Phosphate</td>
<td>4,045,298</td>
<td>4,332,889</td>
<td>↑</td>
</tr>
<tr>
<td>Co-Dydramol</td>
<td>2,949,363</td>
<td>2,757,307</td>
<td>↓</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>1,847,777</td>
<td>1,815,386</td>
<td>↓</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>1,427,507</td>
<td>1,628,120</td>
<td>↑</td>
</tr>
<tr>
<td>Pholcodine</td>
<td>325,909</td>
<td>291,016</td>
<td>↓</td>
</tr>
<tr>
<td>Analgesics with anti-emetics</td>
<td>193,914</td>
<td>194,604</td>
<td>↑</td>
</tr>
<tr>
<td>Co-Proxamol</td>
<td>126,200</td>
<td>105,406</td>
<td>↓</td>
</tr>
<tr>
<td>Co-Phenotrope</td>
<td>36,998</td>
<td>20,061</td>
<td>↓</td>
</tr>
<tr>
<td>Opium and morphine</td>
<td>5,217</td>
<td>4,952</td>
<td>↓</td>
</tr>
<tr>
<td>All other Schedule 5 controlled drugs</td>
<td>8,202</td>
<td>8,520</td>
<td>↑</td>
</tr>
<tr>
<td>Total</td>
<td>24,990,457</td>
<td>24,902,807</td>
<td>↓</td>
</tr>
</tbody>
</table>
Figure 3: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2013 and 2014 (by millions of items)

Nurse and pharmacist prescribing

In 2014, controlled drug prescribing by nurses increased by 12% compared with 2013, and prescribing by pharmacists increased by 56% compared to 2013 in all schedules (table 4). Nurses and pharmacists are principally involved in prescribing methadone and buprenorphine for the treatment of addiction, which accounts for the majority of prescriptions for controlled drugs from these two groups. However, although this still represents only a small proportion of total controlled drug prescribing, we would expect this to increase year-on-year, as non-medical prescribing becomes a better integrated and established means of managing a patient’s condition and providing access to medicines.

Table 4: Nurse and pharmacist prescribing of controlled drugs in NHS primary care (by numbers of items), in 2013 and 2014

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse prescribing</td>
<td>661,544</td>
<td>740,602</td>
<td>↑</td>
</tr>
<tr>
<td>Pharmacist prescribing</td>
<td>29,502</td>
<td>46,037</td>
<td>↑</td>
</tr>
</tbody>
</table>
Private prescribing of controlled drugs

Private prescribing accounts for a small proportion of about 0.06% of overall controlled drug prescribing. The total number of Schedule 2 and 3 controlled drug items prescribed privately in 2014 was 38,913, which is an increase of about 5% compared with 2013 (table 5 and figure 5).

The overall pattern of private prescribing was similar to that reported in 2013. The main points are:

- Methadone continues to be the most common controlled drug prescribed privately, although its use has decreased slightly since 2013 by about 1.6%.
- Tramadol has now made an appearance on the private prescribing list since being re-scheduled from Schedule 4 (part 1) to Schedule 3 in June 2014.
- Lisdexamfetamine is also one of the top 10 controlled drugs prescribed privately following re-scheduling to Schedule 2 in June 2014.
- Private prescribing of methylphenidate during 2014 increased by only 0.4% when compared to 2013. Since 2007, private prescribing of methylphenidate has progressively increased year on year, but the increase in 2014 was noticeably lower than in previous years.
- There was a 16% fall in the number of dexamfetamine prescriptions compared with 2013.
- Temazepam prescribing continued to decrease and fell by a further 19% in 2014.

However, it should also be noted that the data for some private prescribing of controlled drugs is not available through the ePACT system. An example is where the private provider prescribes and supplies the controlled drug directly from the clinic, for example private slimming clinics supplying diethylpropion and phentermine for weight reduction.

Both diethylpropion and phentermine are amphetamine-related chemicals that cause weight loss through suppressing appetite. Diethylpropion is a Schedule 3 controlled drug and its licence was withdrawn in Europe in May 2001 following a European court decision. Phentermine is also a Schedule 3 controlled drug but it is exempt from the need to be stored in a controlled drugs cupboard. They are both at risk of being abused because of their addictive nature. They have poor ‘risk versus benefit’ profiles and are not recommended for the treatment of obesity by either the National Institute for Health and Care Excellence nor the Royal College of Physicians.
Table 5: Top 10 privately prescribed Schedule 2 and 3 controlled drugs (by number of items) in 2013 and 2014

<table>
<thead>
<tr>
<th>BNF chemical substance</th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>13,700</td>
<td>13,482</td>
<td>↓</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>5,151</td>
<td>5,170</td>
<td>↑</td>
</tr>
<tr>
<td>Dexamfetamine</td>
<td>5,191</td>
<td>4,383</td>
<td>↓</td>
</tr>
<tr>
<td>Morpbinne Sulfate</td>
<td>4,145</td>
<td>4,222</td>
<td>↑</td>
</tr>
<tr>
<td>Tramadol †</td>
<td>-</td>
<td>2,390</td>
<td></td>
</tr>
<tr>
<td>Buprenorphine *</td>
<td>2,429</td>
<td>2,320</td>
<td>↓</td>
</tr>
<tr>
<td>Temazepam</td>
<td>2,497</td>
<td>2,028</td>
<td>↓</td>
</tr>
<tr>
<td>Oxycodone **</td>
<td>1,619</td>
<td>1,379</td>
<td>↓</td>
</tr>
<tr>
<td>Lisdexamfetamine ††</td>
<td>90</td>
<td>1,330</td>
<td>↑</td>
</tr>
<tr>
<td>Midazolam †</td>
<td>501</td>
<td>659</td>
<td>↑</td>
</tr>
<tr>
<td>All other Schedule 2 &amp; 3 controlled drugs</td>
<td>1,702</td>
<td>1,550</td>
<td>↓</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>37,025</td>
<td>38,913</td>
<td>↑</td>
</tr>
</tbody>
</table>

* Buprenorphine figures include the combination product Suboxone (buprenorphine and naloxone).  
† Buprenorphine was scheduled as a Schedule 3 controlled drug from June 2014.  
†† Lisdexamfetamine was re-scheduled as a Schedule 2 controlled drug from June 2014.  
* Midazolam figures include oral and injectable midazolam.

Figure 5: Top 10 privately prescribed Schedule 2 and 3 controlled drugs (by thousands of items) in 2013 and 2014 (caveats as in table 4)
Controlled drugs requisitions

Practitioners working in healthcare settings in the community who wish to obtain a stock of a Schedule 2 or 3 controlled drug from a community pharmacy should use a standard Controlled Drug Requisition Form (FP10 CDF). However, use of these forms will not be mandatory until 30 November 2015 and pharmacies can supply controlled drugs requisitioned on non-standard forms. This makes the capturing and analysis of the data more difficult.

Analysis of the requisition data shows that 19,323 controlled drug items were requisitioned in 2014. This is only a small increase (1%) when compared with 2013, where 19,120 controlled drug items were requisitioned. The five most-commonly requisitioned controlled drugs were:

- Oxycodone (4,508 items).
- Morphine Sulfate (3,125 items).
- Fentanyl (2,445 items).
- Midazolam (1,897 items).
- Diamorphine HCl (systemic) (1,700 items).

The majority of requisitions appeared to come from palliative care for people at the end of their lives.

We also looked at variation across NHS England area teams. The highest number of requisitions came from:

- Devon, Cornwall & Isles of Scilly (2,311 items).
- Lancashire (1,934 items).
- Birmingham and the Black Country (1,600 items).
- Surrey & Sussex (1,475 items).
- Cumbria, Northumberland and Tyne & Wear (1,310 items).

Our other main findings were:

The average number of items requisitioned across area teams was 690.

- Lancashire requisitioned the highest number of items of oxycodone at 835 items and Devon, Cornwall & Isles of Scilly was next highest with 523 items. (The average for oxycodone across area teams is 159).
- Morphine sulfate, (opiate), buprenorphine (analgesic), midazolam (anxiolytic) and oxycodone (analgesic) were requisitioned across all area teams.
- Kent & Medway and the South East Coast area teams had the lowest number of requisitions, with 92 and 20 respectively.
The high numbers of requisitions from some area teams may indicate higher use of the mandatory form, which allows more accurate data capture. We are also aware that area teams differ in population size and demographics, which makes it difficult to draw any definitive conclusions from this data. However, future legislative change to make the use of the requisition form mandatory, with exemptions for hospice requisitions, will enable us to access and analyse data more reliably in the future.

Next steps

2014 was a settling down period in which NHS England lead CDAOs worked hard to ensure that the arrangements for the safe management of controlled drugs were maintained following the restructure of the NHS and the changes in regulations during 2013.

Going forward, the further restructure of NHS England must be seen as an opportunity for greater collaboration and consistency across England.
Appendix A: Legislation and regulations


Controlled drugs are a group of medicines that have the potential to be abused. For this reason, they are 'controlled' by The Misuse of Drugs Act 1971. The main purpose of the Act is to prevent the misuse of controlled drugs by imposing restrictions on their possession, supply, manufacture, import and export, as detailed in regulation.

The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 restrict the possession, supply, administration and disposal of controlled drugs.

The legitimate, clinical use of controlled drugs is governed by The Misuse of Drugs Regulations 2001. These divide controlled drugs into five therapeutic ‘schedules’ according to the level of control they need. Further information on the classification and scheduling of controlled drugs can be found here.

Safer management of controlled drugs

The Controlled Drugs (Supervision of Management and Use) Regulations 2013 came into force on 1 April 2013 and superseded The Controlled Drugs (Supervision of Management and Use) Regulations 2006, which were introduced following The Shipman Inquiry. The Department of Health published Information about the 2013 Regulations to provide additional context and guidance.

The regulations require healthcare organisations to appoint a controlled drug accountable officer (CDAO) who has responsibility for all aspects of the management of controlled drugs within their organisation. Smaller organisations may not be required to appoint a CDAO, but must still comply with the Misuse of Drugs Regulations and have arrangements in place to ensure the safe management of controlled drugs and the reporting of controlled drug concerns.

NHS England is also required to appoint CDAOs who are responsible for leading the controlled drug local intelligence networks (CD LINs) for their local geographical area to enable them to share concerns about controlled drugs. They determine the membership of their CD LIN and the frequency of meetings, although they are guided by the Single Operating Model, which provides an operational framework for consistency across England.

Details of all CDAOs in England are held in the Controlled Drugs Accountable Officer Register, which is published on CQC’s website.
Appendix C: Further information

Links to relevant controlled drugs legislation and guidance

The Health and Social Care Act 2012.
The Controlled Drugs (Supervision of Management and Use Regulations 2013.
The Controlled Drugs (Supervision of Management and Use) Regulations 2013 - Information about the regulations.
The Shipman Inquiry Reports.
The Human Medicines Regulations 2012.
NHS England’s Controlled Drugs Accountable Officers’ Single Operating Model.

Newsletters from the Care Quality Commission and NHS England Patient Safety Team

Safe Use of Fentanyl & Buprenorphine Transdermal Patches.
Supporting information.
Preventing Harm from Oxycodone Medicines.
Supporting Information.
Preventing Harm Still Occurring with CDs Administered via MS Syringe Drivers.
Supporting Information.
Preventing harms from the use of methadone.
Supporting information.

Links to CQC’s website for CDAO notifications and the CDAO Register:

Controlled Drugs Accountable Officers
Primary Medical Services Controlled Drugs Myth buster
Controlled drugs governance self assessment tool for primary care organisations
Controlled drugs governance self assessment tool for secondary care organisations
Information for service providers

Whether you are the owner of a new organisation and need to register with us, or if you work for an existing registered provider, you can find everything you need on our website in our Guidance for providers.

Registering for the first time

Find out how to apply to register as a new provider or registered manager of a health or social care service by following our quick step-by-step guides.

Step-by-step guide to applying as a new provider.
Step-by-step guide to applying as a new registered manager.

Already registered?

If you have already registered with CQC as a provider or manager and would like guidance on meeting the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (which include the new fundamental standards), see our Guidance on meeting the regulations.

How to contact us

If you need further assistance with a Register enquiry or you want to notify us of a change of contact details for your CDAO (phone number or email address), please email us at CDAOregisterdata@CQC.org.uk.
## Glossary of terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accountable officer (AO) Controlled drugs accountable officer (CDAO)</td>
<td>The person in a healthcare organisation who takes formal responsibility for all controlled drug handling and governance issues in their organisation. This is a requirement under the Health Act 2006. Details of the role are set out in the Controlled Drugs (Supervision of Management and Use) Regulations 2006.</td>
</tr>
<tr>
<td>Clinical commissioning group (CCG)</td>
<td>Groups of GP practices responsible for working with other healthcare professionals to commission most health and care services for patients. CCGs replaced PCTs from 1 April 2013.</td>
</tr>
<tr>
<td>Commissioning support unit (CSU)</td>
<td>Commissioning support units provide clinical commissioning groups with external support, specialist skills and knowledge to support them in their role as commissioners.</td>
</tr>
<tr>
<td>Controlled drugs liaison officer (CDLO)</td>
<td>Police officer or police staff with a specific role in relation to controlled drugs intelligence and investigation.</td>
</tr>
<tr>
<td>Controlled drug designated body (CDDB)</td>
<td>A healthcare organisation that is required to have an accountable officer under the Controlled Drugs (Supervision of Management and Use) Regulations 2006. In England this includes NHS trusts (including foundation trusts) and independent hospitals.</td>
</tr>
<tr>
<td>Controlled drug requisitions</td>
<td>Standardised documents that are used when healthcare practitioners requisition supplies of controlled drugs from community pharmacies.</td>
</tr>
<tr>
<td>Electronic Prescribing Analysis and Costs (ePACT)</td>
<td>A computer system that provides an interface to analyse prescribing information held on the NHS Prescription Services’ prescription information database.</td>
</tr>
<tr>
<td>FP10PCD</td>
<td>Standardised controlled drugs private prescription form.</td>
</tr>
<tr>
<td>Local intelligence network (LIN or CD LIN)</td>
<td>Defined in legislation as a network to share information between organisations and agencies regarding the handling and use of controlled drugs.</td>
</tr>
<tr>
<td>NHS England</td>
<td>Known as the ‘NHS Commissioning Board’ Before 1 April 2013, and in the Health and Social Care Act 2012.</td>
</tr>
<tr>
<td>Responsible body</td>
<td>Body or organisation defined in regulation with a duty to share information about controlled drugs.</td>
</tr>
</tbody>
</table>
How to contact us

Call us on: 03000 616161
Email us at: enquiries@cqc.org.uk
Look at our website: www.cqc.org.uk
Write to us at: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

Follow us on Twitter: @CareQualityComm

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