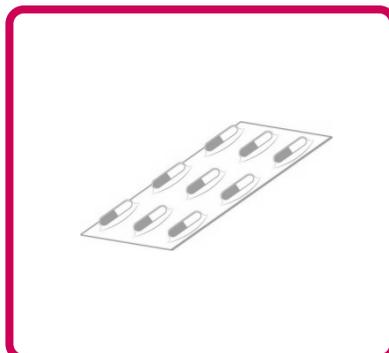
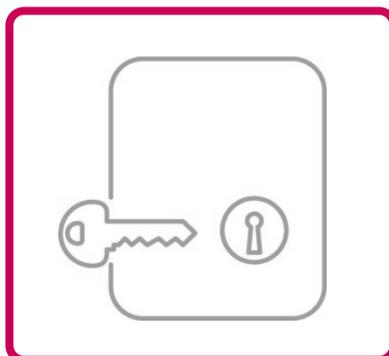


The safer management of controlled drugs

Annual report 2015

July 2016



The Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care in England. We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

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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Summary and recommendations

In this, our ninth report, we make three recommendations to strengthen existing arrangements for the reporting and sharing of controlled drug concerns across England. We showcase local and national initiatives to promote the safe use of controlled drugs and to reduce harm from their misuse. The report also includes an overview of prescribing data and identifies prescribing trends.

As well as our responsibilities under the Health and Social Care Act 2008, the Care Quality Commission (CQC) is responsible for making sure that health and adult social care providers, and other regulators, maintain a safe environment for the management of controlled drugs in England. This came 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 2015 under these regulations to ensure safe arrangements for controlled drugs. It also reports on data for 2015 on prescribing of controlled drugs across England in the primary care sector, and identifies any trends in prescribing.

One of CQC's responsibilities under the regulations is to maintain and publish a 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 2015 continued to be low. CQC also continued to chair the National Group on Controlled Drugs, which met four times during 2015, and established four sub-groups to focus on a number of key areas – namely thefts and frauds, patient safety, policy and operational issues and prescribing. 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 strategic controlled drugs-related issues across our borders.

Another responsibility for CQC is to have oversight of how well local controlled drug intelligence networks (CD LINS) across England are working. Following NHS England's re-alignment review during the first part of 2015, the number of NHS England area teams reduced from 27 to 13, which resulted in a period of re-adjustment for some CD LINS. This caused some initial concern because of the size of some of the regions that each NHS England CDAO was responsible for. However, it has worked well in practice and the lead CDAOs are now working more collaboratively, resulting in greater consistency across England when sharing both concerns and good practice around controlled drugs. However, there is still more work to do in order to obtain a national picture.

Key legislation changes and national trends in the use and management of controlled drugs during 2015

- Electronic prescribing of Schedules 2 and 3 controlled drugs is now permitted where the Electronic Prescription Service (EPS) is used.
- Physiotherapist and podiatrist independent prescribers are able to prescribe a limited range of controlled drugs for the treatment of disease or injury.
- Ketamine became a Schedule 2 controlled drug (with exemptions for specific health professionals under Patient Group Directions).
- Standardised requisition forms for Schedules 2 and 3 controlled drugs became mandatory. (The Home Office has published additional guidance on the NHS BSA website following implementation queries.)

In 2015, a total of 60,577,367 controlled drugs items were prescribed in NHS primary care, which is a decrease of 0.48% compared with 2014. The cost of this was £561,872,673.58, an increase of 2.41% on the £548,634,970.00 spent in 2014. In addition, a further 1,118,884 items were prescribed in hospital using an FP10(HNC) or an FP10SS form to be dispensed in the community. Prescribing of Schedules 2 and 3 controlled drugs in primary care stayed broadly comparable with 2014, with an overall decrease of 0.3% in items prescribed.

Controlled drug prescribing by nurses increased by 12% compared with 2014, which is broadly in line with increases in previous years. Furthermore, prescribing by pharmacists increased by 112% compared with 2014 in all schedules. This reflects changes in practice, for example, the increasing numbers of independent prescribers working in primary care.

As in previous years, private prescribing accounted for only a small proportion (0.06%) of overall controlled drug prescribing. The total number of Schedules 2 and 3 controlled drug items prescribed privately in 2015 was 39,504, which is an increase of about 1.5% compared with 2014.

The use of a standardised controlled drug requisition form became mandatory on 30 November 2015. The form must be used by practitioners working in healthcare settings in the community who wish to obtain a stock of a Schedule 2 or 3 controlled drug and is accessed on the NHS BSA website. Hospices and prisons are exempt from this requirement. In time, use of this form will make it easier to capture and analyse requisition data, but at the moment there is inevitably a settling down period and a number of issues have been brought to the attention of the Home Office for further consideration. The data that we have shows 19,493 controlled drug items were requisitioned in 2015, which is only a small increase of 0.9% compared with 2014.

Recommendations

We make the following recommendations for NHS England CDAOs, CDAOs in all organisations, and local authorities.

NHS England CDAOs should agree on and collect consistent information on controlled drug-related issues to provide a national picture.

All CDAOs should support the NHS England CDAOs by providing information requested of them in a timely way so that the CD LINs function effectively and productively.

Local authorities, through their Public Health and Adult Social Care Directors, should engage with their CD LINs to share concerns about controlled drugs that relate to the services they commission – in particular, social care organisations and drug and alcohol services.

What CQC will do

As a regulator of health and adult social care services, we are currently looking at how we can use the information provided in the alerts generated from CD LINs more effectively to inform our inspection teams and guide the focus of inspections. We have therefore committed to share these alerts with the appropriate local inspection teams.

Progress on recommendations made in the 2014 report

In our previous report published in July 2015, we made six recommendations to improve the management of controlled drugs.

Recommendation	Progress
<p>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.”</p>	<p>We have identified and contacted a number of smaller organisations to make them aware of the ‘exemption’ criteria.</p>
<p>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.”</p>	<p>NHS England lead CDAOs are now working much more collaboratively.</p>
<p>“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.”</p>	<p>Co-commissioning and other arrangements have now superseded this recommendation but NHS England is asking CCGs to consider their responsibilities in this area.</p>
<p>“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.”</p>	<p>Progress has been variable across the country and in some areas, there has been good joined-up working between local authorities and CCGs.</p>
<p>For NHS England “NHS England should provide guidance for occurrence reporting so that organisations understand what they need to report to the CD LIN.”</p>	<p>There was little evidence of progress during 2015. However, we are aware that the NHS England CDAOs are currently working on this as a priority area.</p>
<p>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.”</p>	<p>There has been a real focus on learning at LINs during 2015 and some Medication Safety Officers (MSOs) now attend LINs. However, we have been unable to capture how well CDAOs are working with their MSOs at an organisational level.</p>

The Care Quality Commission's activity in 2015

CQC's website

We have updated the [dedicated controlled drug section](#) on CQC's website to include [guidance](#) that explains which organisations need a controlled drugs accountable officer (CDAO) and which are exempt, the criteria that must be met to be appointed as a CDAO and how different types of organisations can notify us about changes.

The web pages also include the online [register of CDAOs](#), [links to legislation and supporting information](#) and [newsletters from sub-groups of the Controlled Drugs National Group](#). We also provide information regarding controlled drugs in primary medical services in the [Controlled drugs myth-buster](#).

Register of controlled drug accountable officers

In 2015, CQC continued to maintain and publish a monthly register of CDAOs across England for those organisations that are required under the 2013 Regulations to have a CDAO. These organisations are defined as designated bodies under the regulations and are required to notify CQC of their CDAO appointment. We received approximately 25 CDAO notifications each month.

Throughout the year we had an average of 963 organisations on our CDAO Register. Of those organisations: 694 CDAOs were from independent healthcare organisations, 240 were from NHS organisations and the remainder were from other organisations such as social care providers that fall within the 'designated body' status.

We continued to grant CDAO exemptions for independent healthcare organisations with more than 10 staff but with a low controlled drugs usage, as it would be disproportionate to appoint someone. Organisations with fewer than 10 employees are automatically exempted. However, the uptake of the CDAO exemption by eligible organisations remains low, and in 2015 we received and approved only six CDAO exemptions.

To ensure that our published register remains as accurate as possible, we undertake regular quality assurance checks. These include a monthly data quality check and further cross checking to identify organisations that should have a CDAO appointed but for which we have not received a notification. Where this is the case, we follow up with the organisation concerned. We also follow up smaller services that might be eligible for a CDAO exemption. Our findings from this work show that whilst some organisations fit the CDAO exemption criteria, they preferred not to apply, citing that having a CDAO in place strengthens their organisational controlled drug governance processes.

NHS England-led controlled drug local intelligence networks

Following an internal review within NHS England, the number of NHS England areas, and therefore number of NHS England lead CDAOs, decreased on 1 April 2015 from 27 to 13. Together with the inevitable associated staff changes, this meant that the first half of 2015 was yet again a time of re-adjustment for some controlled drug local intelligence networks (CD LINs). Although this means that fewer lead CDAOs now have larger areas to cover, it has meant that they can meet and work more collaboratively. However, their capacity to look at issues at a local level has diminished further.

There has been progress in updating the Single Operating Model (SOM), the framework under which the NHS England CDAOs operate, but this has not yet been completed. 2015 was very much a settling down period for the new team of NHS England CDAOs and they are all working together to produce an updated framework.

CQC attended 86 CD LIN meetings across all area teams during 2015, which is broadly similar to the number attended in 2014. Regular meetings continue, although we have noted that in some areas their frequency has been reduced from four to three or two times a year, with a corresponding small increase in meeting length. This is not necessarily a bad thing as members continue their good attendance and engagement. There is good associated learning at local meetings and in some areas we have attended excellent regional learning events, which commonly include external speakers and networking opportunities.

We have also noted improved communication by lead CDAOs to LIN members through newsletters and sharing alerts across LINs. As a regulator, CQC is currently looking at how we can use the information provided in the alerts generated from CD LINs more effectively to inform our inspection teams and guide inspections.

Although the majority of CD LINs also now have noticeably wider memberships with most members engaging fully, some do not. Local authority attendance remains an issue in many areas and we urge them to be more involved. Their input is particularly valuable as they commission social care and drug and alcohol services across their area.

RECOMMENDATION

Local authorities, through their Public Health and Adult Social Care Directors, should engage with their CD LINs to share concerns about controlled drugs that relate to the services they commission – in particular, social care organisations and drug and alcohol services.

Occurrence reporting

There was little progress with developing a nationally-agreed occurrence reporting data set during 2015, but we are aware that NHS England lead CDAOs are working on this. As the regulations are due for review in 2020, it would be helpful to have two to three years' worth of data to feed into that process.

RECOMMENDATIONS

NHS England CDAOs should agree on and collect consistent information on controlled drug-related issues to provide a national picture.

All CDAOs should support the NHS England CDAOs by providing information requested of them in a timely way so that the CD LINs function effectively and productively.

Examples of good practice from CD LINs

When we attend CD LIN meetings, we ask members to share any examples of good practice with us, so that we can share the learning more widely with other organisations. The following are some of the examples we saw in 2015.

1: NHS England North Midlands Region

Controlled drug self-declaration and self-assessment in special schools

NHS England North Midlands has been working to identify what governance arrangements are in place for controlled drugs in special schools.

The team issued a controlled drug self-declaration and self-assessment form to all special schools in their area. To date, the submitted declarations have shown that the schools have robust measures in place to manage their pupils' controlled drugs. However, the self-assessment has highlighted the need for additional support and advice, particularly around arrangements when pupils are travelling to and from school on organised school transport and when they are attending activities away from the school site.

2: NHS England North Midlands Region

Controlled drugs audit in dispensing practices

NHS England North Midlands has used CQC's primary care self-assessment tool to seek assurance of the controlled drug arrangements in its local dispensing practices and to identify what support or advice they might need.

The audit tool consisted of 39 questions covering key areas of controlled drugs governance such as:

- standard operating procedures (SOPs)
- controlled drugs on premises and in transport
- monitoring and auditing controlled drug arrangements
- processes for the destruction of controlled drugs, including witnessing
- recording and investigating concerns
- staff training.

The tool used the RAG (red, amber, green) rating system to evaluate responses, with red and amber responses requiring an action plan with timescales. Some of the areas that needed action included:

- SOPs: not all areas of controlled drug management were adequately covered, with gaps relating to key handling, transporting and delivering controlled drugs and the CDAO function.
- How to deal with incidents and who to report concerns/incidents to.
- Stock checks and record keeping.
- Some practices had also accumulated out-of-date stock as they were unsure what to do about destruction and how to contact the Authorised Witness. They were similarly unclear about returns from patients.

The dispensing practices welcomed the audit, and found it a useful exercise to review and strengthen their governance arrangements for controlled drugs. The work has also enabled the controlled drugs team to improve links and strengthen working relationships with dispensing practice staff.

3: Aintree University Hospital NHS Trust

Electronic controlled drug ordering on wards

Aintree Hospital has designed and implemented an electronic ordering system for controlled drugs. The ordering process eliminates the need for transcription at any point in the supply process, which means that there is no need for staff to enter data when labelling or inputting on the controlled drug register. The nurse creates an order from the electronic prescribing system and this order passes electronically through pharmacy stock control and into the controlled drug register/Omniceil. Safeguards are in place to ensure that only authorised nurses can place orders and that orders are correct. There is a robust audit process to allow ward managers to know who in their teams is placing orders and how frequently.

For more information about any of these examples, please email CQC's Controlled Drug team CDAOregisterdata@CQC.org.uk.

Controlled Drugs National Group

The CQC-led Controlled Drugs National Group (comprising key regulators and agencies with a controlled drugs remit) continued to meet quarterly in 2015 to share and discuss emerging issues and to identify ways of working together to reach solutions. Following positive feedback, we are continuing to share a condensed version of the meeting minutes with NHS England lead CDAOs so that they can share with CD LIN members to keep them informed of controlled drug-related developments and policy initiatives.

Membership of the group remained the same as in 2014 and alongside this main report, we have published a separate [summary 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 examples of national initiatives in which some of our members have been involved.

Pain management formulary in prisons

The Prison Healthcare Board (England) approved a programme of work, hosted by the NHS England Health and Justice Clinical Reference Group, to deliver a recommended national pain management formulary for use in HM Prisons. The formulary supports clinicians in the management of acute or persistent pain and neuropathic pain, taking account of the specific challenges of prescribing pain medicines in prisons. The formulary is published as two documents that should be used together to embed the formulary into practice. The formulary can be found on [NHS England's website](#).

Opioids Aware

This is a new online resource to support the safe and rational use of opioids for pain. It was developed collaboratively between a number of organisations including several medical royal colleges, NICE, CQC, the British Pain Society and the Royal Pharmaceutical Society. The resource contains specific information relating to the clinical use of opioids for pain, which aims to support prescribers and patients when making a fully informed decision on whether or not to use opioids. The resource is available at:

www.fpm.ac.uk/faculty-of-pain-medicine/opioids-aware.

In addition to the National Group, we also formed four additional sub groups to look specifically at key areas of work in the second half of 2015. The four groups are:

- Controlled drugs vigilance sub group (focuses on thefts and frauds and what to look out for)
- Controlled drugs patient safety sub group (formerly known as the clinical sub group, which aims to promote safe clinical practice relating to controlled drugs)
- Controlled drugs policy and operational issues sub group (tackling the practicalities)
- Controlled drugs prescription monitoring sub group (focuses on a national overview of controlled drug prescribing).

The sub groups meet in person or by teleconference every few months as required. Membership comprises relevant stakeholders, such as NHS Protect and the police, specialist pharmacists and Medicine Safety Officers (MSOs), other government bodies, the NHS Information Centre, NHS England CDAOs and chief pharmacists. Other healthcare professionals with relevant expertise are also invited as required.

Each sub group produces a newsletter that includes links to relevant guidance and case studies, and is available on the controlled drug pages on CQC's website [here](#). As always, we welcome your feedback and input through the mailbox CDsubgroups@cqc.org.uk.

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2015. It includes the Controlled Drugs Accountable Officers' Network Scotland (CDAON), the Health and Social Care Board of Northern Ireland, NHS Wales and the Health Products Regulatory Authority (HPRA) of Ireland. The group continues to provide a forum to discuss controlled drug matters at a strategic level and we have published a [separate summary](#) of their major activities during 2015.

National trends in the use and management of controlled drugs

During 2015, the total number of controlled drug items prescribed in NHS primary care was 60,577,367, which was a decrease of 0.48% compared with 2014. However, the cost of this was £561,872,673, which is an increase of 2.41% on the £548,634,970 spent in 2014.

As well as this, a total of 1,118,884 controlled drug items across Schedules 2 to 5 were prescribed in hospital using an FP10(HNC) or FP10SS form to be dispensed in the community during 2015. In general, the prescribing was broadly in line with that of primary care prescribing of controlled drugs.

Schedule 1 controlled drugs

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

Schedules 2 and 3 controlled drugs

Prescribing of Schedules 2 and 3 controlled drugs in primary care in 2015 stayed broadly comparable with 2014 (table 1 and figure 1). Overall, Schedules 2 and 3 controlled drugs saw a 0.3% decrease in items prescribed during 2015 compared with 2014.

Compared with 2014, there were increases in the volume of items prescribed for: midazolam (10.1%), oxycodone (9.9%), methylphenidate (8.7%), morphine sulfate (7.0%), buprenorphine (5.2%), and fentanyl (1.9%).

There were also decreases in volumes of items prescribed for: temazepam (15.2%), phenobarbital (4.7%), tramadol (4.6%) and methadone (1.4%) compared with 2014.

As seen in previous years, methylphenidate prescribing continued to increase steadily during 2015. The increase is likely to be attributable to a greater recognition of attention deficit hyperactivity disorder (ADHD) by GPs. Until a few years ago, methylphenidate prescribing was low with the view that this was because ADHD was under-diagnosed. However, there may now be some over-prescribing of methylphenidate and we are aware that it is also subject to misuse. Analysis into its increase continues.

Prescribing of temazepam has continued to decline since 2007, with a 15% decline in items prescribed during 2015 compared with 2014.

Tramadol, as outlined above, saw a small decrease in prescribing. This may be a result of its rescheduling in 2014 as a Schedule 3 controlled drug.

Table 1: Top 10 Schedules 2 and 3 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by number of items)

Top 10 Schedules 2 & 3 controlled drugs	Total items 2014	Total items 2015	Change
Tramadol	7,888,685	7,526,285	↓
Buprenorphine*	2,644,760	2,782,977	↑
Morphine sulfate	2,406,166	2,574,761	↑
Methadone	2,009,688	1,981,888	↓
Oxycodone**	1,353,362	1,486,899	↑
Temazepam	1,666,775	1,412,926	↓
Fentanyl∞	1,203,660	1,226,659	↑
Methylphenidate	793,749	862,639	↑
Midazolam♦	213,125	234,709	↑
Phenobarbital	236,850	225,658	↓
<i>All other Sch 2 & 3 controlled drugs</i>	<i>314,309</i>	<i>351,059</i>	<i>↑</i>
Total	20,731,129	20,666,460	↓

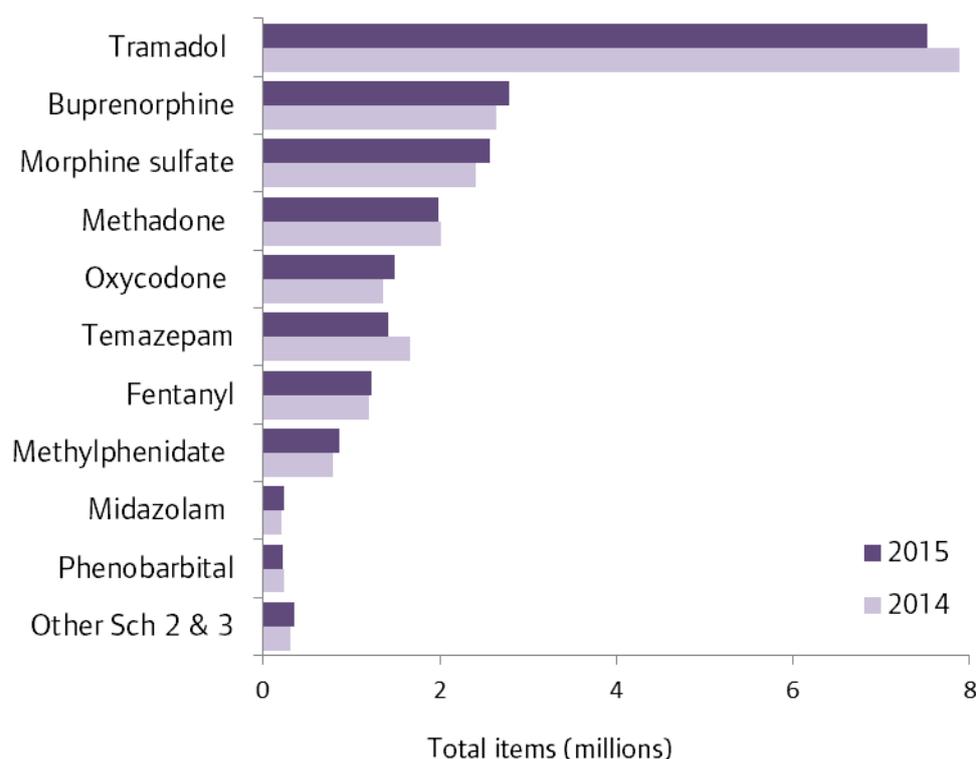
* Buprenorphine figures include the combination buprenorphine/naloxone.

** 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 and midazolam maleate.

Figure 1: Top 10 Schedules 2 and 3 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by millions of items) (caveats as in table 1)



Schedule 4 controlled drugs

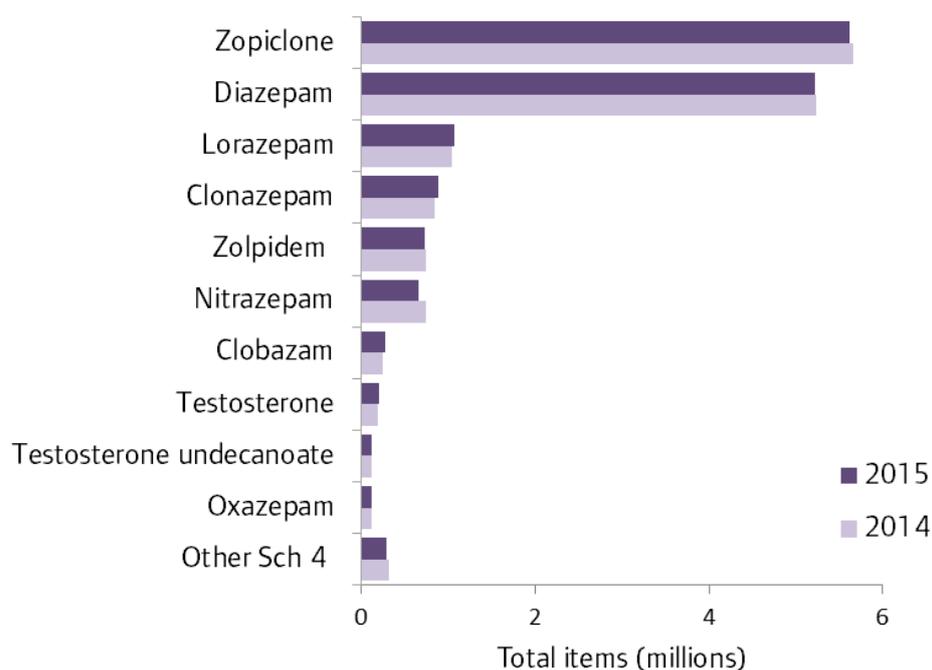
The pattern of prescribing for Schedule 4 controlled drugs during 2015 remains broadly similar to 2014, with the overall items prescribed seeing a small decrease of 0.61% compared with 2014. Figure 2 shows the profile of prescribing for Schedule 4 controlled drugs during 2015.

Table 2: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by number of items)

Top 10 Schedule 4 controlled drugs	Total items 2014	Total items 2015	Change
Zopiclone	5,657,585	5,613,129	↓
Diazepam	5,239,813	5,221,559	↓
Lorazepam	1,046,808	1,067,796	↑
Clonazepam	835,655	880,766	↑
Zolpidem	734,934	726,545	↓
Nitrazepam	734,578	658,619	↓
Clobazam	248,602	266,487	↑
Testosterone	187,503	200,465	↑
Testosterone undecanoate *	110,025	116,274	↑
Oxazepam	121,957	113,277	↓
<i>All other Sch 4 controlled drugs</i>	<i>319,910</i>	<i>279,696</i>	↓
Total	15,237,370	15,144,613	↓

*Testosterone undecanoate has entered the top 10 Schedule 4 controlled drugs, moving chlorthalidone out of the top 10 into 11th place. This now means two of the five testosterone products within Schedule 4 are now in the top 10.

Figure 2: Top 10 Schedule 4 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by millions of items)



Schedule 5 controlled drugs

The pattern of prescribing for Schedule 5 controlled drugs during 2015 remains broadly similar to 2014, with the overall items prescribed seeing a small decrease of 0.5% compared with 2014. Figure 3 shows the profile of prescribing for Schedule 5 controlled drugs during 2015.

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.

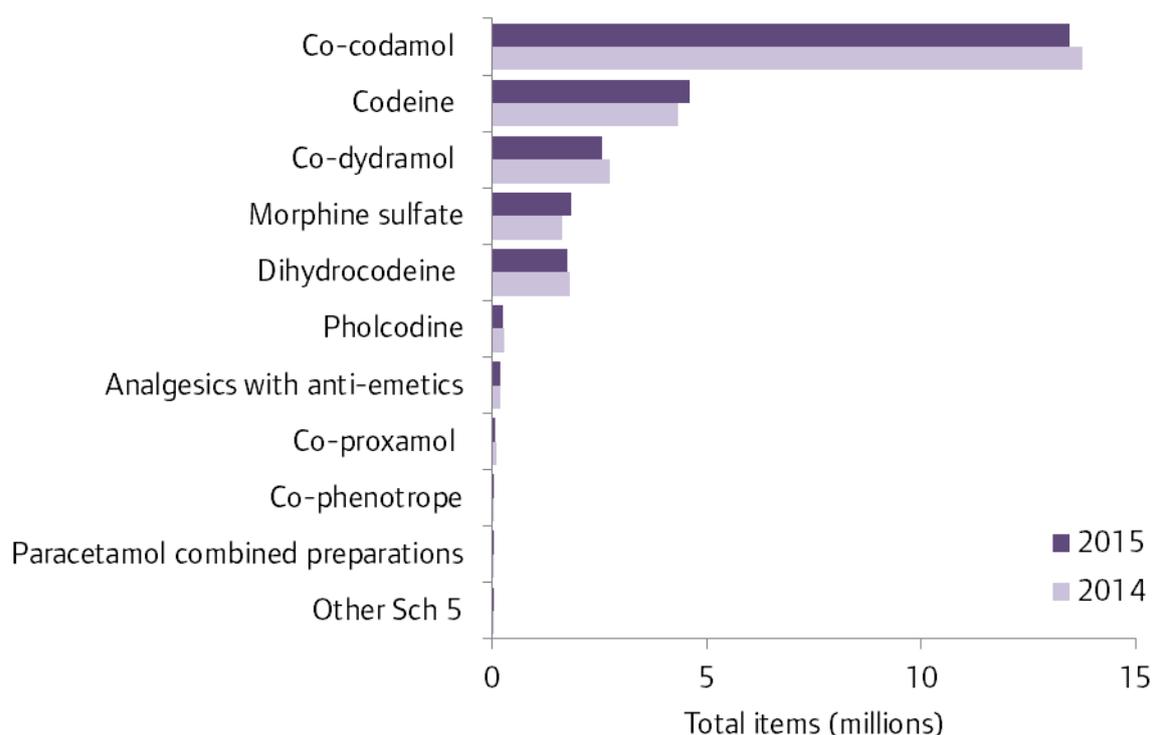
The most commonly prescribed Schedule 5 item continues to be co-codamol (combination of paracetamol and a low dose of the weak opioid, codeine), which accounts for 54% of prescribing in this group.

Table 3: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by number of items)

Top 10 Schedule 5 controlled drugs	Total items 2014	Total items 2015	Change
Co-codamol	13,744,546	13,471,262	↓
Codeine	4,332,889	4,603,813	↑
Co-dydramol	2,757,307	2,549,734	↓
Morphine sulfate	1,628,120	1,831,247	↑
Dihydrocodeine	1,815,386	1,766,984	↓
Pholcodine	291,016	253,669	↓
Analgesics with anti-emetics	194,604	186,017	↓
Co-proxamol	105,406	82,408	↓
Co-phenotrope	20,061	8,780	↓
Paracetamol combined preparations*	4,583	4,626	↑
<i>All other Sch 5 controlled drugs</i>	8,889	7,754	↓
Total	24,902,807	24,766,294	↓

* Includes Solpadeine, Ultramol and Syndol.

Figure 3: Top 10 Schedule 5 controlled drugs prescribed in NHS primary care in 2014 and 2015 (by millions of items) (caveats as in table 3)



Nurse and pharmacist prescribing

In 2015, controlled drug prescribing by nurses increased by 12% compared with 2014, which is broadly in line with increases in previous years (table 4). In contrast, prescribing by pharmacists increased by 112% compared with 2014 in all schedules.

In the past, nurses and pharmacists have principally been involved in prescribing methadone and buprenorphine for the treatment of addiction. Although this is still true (20% of all nurse prescribing was for methadone and 9% for buprenorphine, and 7% of all pharmacist prescribing was for methadone and 5% for buprenorphine) the most commonly prescribed medicine by these two groups now is co-codamol. This reflects changes in practice, for example, the increasing numbers of independent prescribers working in primary care.

Table 4: Nurse and pharmacist prescribing of controlled drugs in NHS primary care (by numbers of items), in 2014 and 2015

	2014	2015	Change
Nurse prescribing	906,757	1,014,085	↑
Pharmacist prescribing	60,085	127,547	↑

Note: The 2014 figures above are different to those published in CQC's annual report on controlled drugs for 2014. The published 2014 figures were reconciled to account for changes in schedules for tramadol, lisdexamfetamine, zopiclone and zaleplon during 2014.

In 2015, the top drug item prescribed for both nurse and pharmacist prescribing was co-codamol, accounting for 25% of all nurse-prescribed items for all schedules and 20% of prescribing by pharmacists. For nurse prescribing, tramadol accounts for 7% of prescribed items and codeine 9%, which along with co-codamol, accounts for 40% of prescribed items in 2015 for all schedules. Tramadol accounts for 12% of pharmacist prescribing and codeine 8%, which along with co-codamol, accounts for 41% of pharmacist prescribing for 2015.

Physiotherapist and chiropodists/podiatrists prescribing

Prescribing of controlled drugs by physiotherapists and podiatrists was minimal during 2015, with fewer than 100 items prescribed in total. The most commonly prescribed controlled drugs were those in Schedule 5.

Private prescribing of controlled drugs

Private prescribing accounts for a small proportion (0.06%) of overall controlled drug prescribing. The total number of Schedules 2 and 3 controlled drug items prescribed privately in 2015 was 39,504, which is an increase of about 1.5% compared with 2014 (table 5 and figure 4). While overall in 2015 the top 10 controlled drugs remained broadly the same as for 2014, the volumes of items prescribed varied year on year.

- Methadone continues to be the most common controlled drug prescribed privately, although its use has continued to decrease (by 21% in 2015 compared with 2014).
- Prescribing for attention deficit hyperactivity disorder (ADHD) continues to increase, with methylphenidate prescribing in 2015 up by 39% compared with 2014, now making it the second most common controlled drug in Schedules 2 and 3 prescribed privately. Lisdexamfetamine prescribing has also increased, while conversely dexamfetamine prescribing has slightly decreased.
- Private prescribing of tramadol during 2015 saw a 13% decrease compared with 2014. This is in line with the decrease in primary care prescribing of tramadol seen in 2015.
- Temazepam also continued a downward trend, with a 16% decrease in privately prescribed items in 2015 compared with 2014.
- Fentanyl is now in the top 10 of Schedules 2 and 3 controlled drug items prescribed privately in 2015, replacing midazolam, which is now at number 11.

It is important to note that the data for some private prescribing of controlled drugs is not available through the ePACT system, such as where a 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 are Schedule 3 controlled drugs and are amphetamine-related chemicals that cause weight loss by suppressing appetite. The licence for diethylpropion was withdrawn in Europe in May 2001 after a European court decision. Although it is a Schedule 3 controlled drug, phentermine is exempt from the need to be stored securely in a controlled drugs cupboard. They are both at risk of being misused because of their addictive nature.

They have poor 'risk versus benefit' profiles and are not recommended for treating obesity by either the National Institute for Health and Care Excellence or the Royal College of Physicians.

Table 5: Top 10 privately prescribed Schedules 2 and 3 controlled drugs (by number of items) in 2014 and 2015

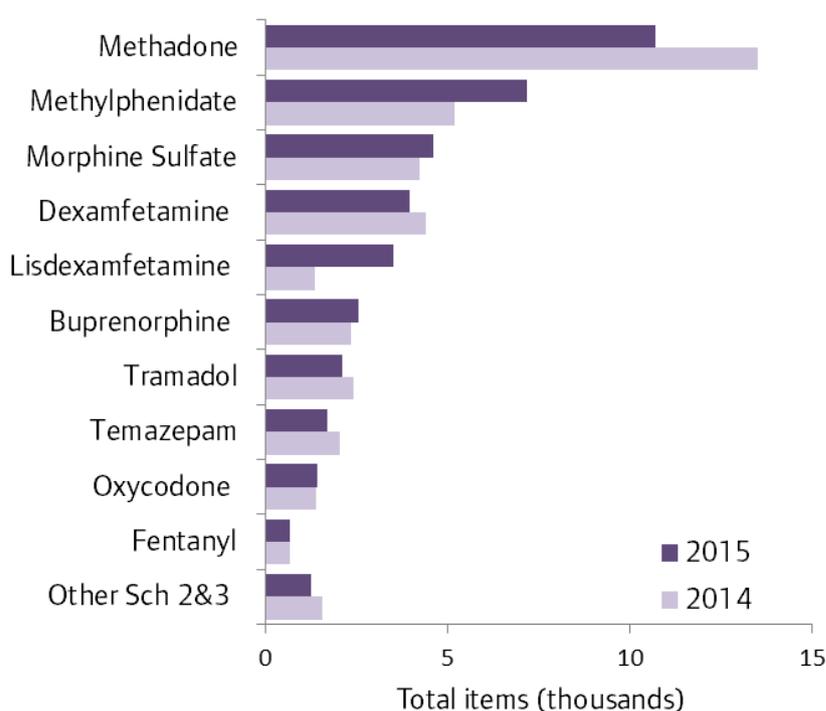
Top 10 privately prescribed Schedules 2 & 3 controlled drugs	Total items 2014	Total items 2015	Change
Methadone	13,482	10,701	↓
Methylphenidate	5,170	7,167	↑
Morphine sulfate	4,222	4,598	↑
Dexamfetamine	4,383	3,933	↓
Lisdexamfetamine	1,330	3,498	↑
Buprenorphine*	2,320	2,549	↑
Tramadol	2,390	2,080	↓
Temazepam	2,028	1,696	↓
Oxycodone**	1,379	1,398	↑
Fentanyl***	654	655	↑
All other Sch 2 & 3 controlled drugs	1,555	1,229	↓
Total	38,913	39,504	↑

*Buprenorphine figures include the combination product Suboxone (buprenorphine and naloxone).

**Oxycodone figures include the combination product Targinact (oxycodone and naloxone).

*** Fentanyl figures include fentanyl transdermal patches and small amounts of other fentanyl products.

Figure 4: Top 10 privately prescribed Schedules 2 and 3 controlled drugs (by thousands of items) in 2014 and 2015 (caveats as in table 6)



Controlled drugs requisitions 2014 to 2015

Practitioners working in healthcare settings in the community who wish to obtain a stock of a Schedule 2 or 3 controlled drugs from a community pharmacy must now use a standard Controlled Drug Requisition Form (FP10 CDF). Use of these forms was not mandatory until 30 November 2015 and pharmacies were previously able to supply controlled drugs requisitioned on non-standard forms.

To date, there is only a limited amount of data available as the mandatory form was not introduced until late 2015. Analysis of the requisition data shows that 19,493 controlled drugs items were requisitioned in 2015, which is a 0.9% increase when compared with 2014 where 19,323 were requisitioned. Of the requisitioned items, 61% came from NHS requests and 39% were from private prescribing.

The five most commonly requisitioned controlled drugs for 2015 were:

- oxycodone (3,813 items)
- morphine sulfate (3,291 items)
- tramadol (2,324 items)
- fentanyl (1,973 items)
- midazolam (1,756 items).

Next steps

2015 was a further year of adjustment in which NHS England lead CDAOs worked hard to ensure that the arrangements for the safe management of controlled drugs were maintained following the organisational changes within NHS England. Furthermore, the continuing changes to the way in which healthcare is delivered across England add to their challenges, particularly in the management of CD LIN membership. However, there is now a much more joined-up approach across England.

Going forward, we need to continue to monitor how the regulations are implemented to ensure that arrangements remain effective. We also need consistent reporting arrangements to establish a national picture of controlled drug incidents.

Appendix A: Legislation and regulations

Home Office controlled drugs legislation: The Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001

Controlled drugs are a group of medicines that have the potential to be misused. 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.

Both 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 on the Home Office website [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 B: 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](#)

[The Misuse of Drugs Act 1971](#)

[The Misuse of Drugs Regulations 2001](#)

[The Misuse of Drugs \(Amendment\) \(No. 2\) \(England, Wales and Scotland\) Regulations 2015](#)

[NHS England's Controlled Drugs Accountable Officers' Single Operating Model](#)

[NICE Guideline 46: The safe use and management of controlled drugs](#)

Links to key changes in controlled drugs legislation during 2015

Electronic prescribing of Schedules 2 and 3 controlled drugs:

- [The National Health Service \(Amendments to Primary Care Terms of Service relating to the Electronic Prescription Service\) Regulations 2015](#)
- [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2015](#)

[Physiotherapist and podiatrist independent prescribers](#)

[Rescheduling of ketamine](#)

[Standardised requisition forms for Schedules 2 and 3 controlled drugs](#)

Newsletters of the Controlled Drugs National Group Sub Group

[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](#)

[Vigilance newsletter](#)

[Patient Safety newsletter](#)

Other newsletters on policy and prescribing will be available on the [website](#).

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

Follow our quick step-by-step guides on registering as a new provider or registered manager of a health or social care service:

[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 (including the fundamental standards), see our [Guidance on meeting the regulations](#).

How to contact us

If you have an enquiry about the register 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

Term	Definition
Controlled drugs accountable officer (AO or CDAO)	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.
Controlled drugs liaison officer (CDLO)	Police officer or police staff with a specific role in relation to controlled drugs intelligence and investigation.
Controlled drug designated body (CDDB)	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.
Controlled drug requisitions	Standardised documents that are used when healthcare practitioners requisition supplies of controlled drugs.
Electronic Prescribing Analysis and Costs (ePACT)	A computer system that provides an interface to analyse prescribing information held on the NHS Prescription Services' prescription information database.
Electronic Prescription Service (EPS)	An electronic system that enables prescribers such as GPs and practice nurses to send prescriptions electronically to a pharmacy of the patient's choice.
FP10PCD	Standardised controlled drugs private prescription form.
Local intelligence network (LIN or CD LIN)	Defined in legislation as a network to share information between organisations and agencies regarding the handling and use of controlled drugs.
Responsible body	Body or organisation defined in regulation with a duty to share information about controlled drugs.

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Published July 2016

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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**



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